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REVIEW OF THE FY 2021 BUDGET AND FY 2022 ADVANCE APPROPRIATIONS REQUEST AND OVERSIGHT OF CARES ACT SUPPLEMENTAL APPROPRIATIONS FOR THE DEPARTMENT OF VETERANS AFFAIRS

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

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JUNE 3, 2020

SENATORS

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REVIEW OF THE FY 2021 BUDGET AND FY 2022 ADVANCE APPROPRIATIONS REQUEST AND OVERSIGHT OF CARES ACT SUPPLEMENTAL APPROPRIATIONS FOR THE DEPARTMENT OF VETERANS AFFAIRS

WEDNESDAY, JUNE 3, 2020

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 3:12 p.m., in room SD–106, Dirksen Senate Office Building, Hon. Jerry Moran presiding.

Present: Senators Moran, Boozman, Cassidy, Rounds, Tillis, Sullivan, Loeffler, Tester, Brown, Blumenthal, Hirono, Manchin, and Sinema.

OPENING STATEMENT OF CHAIRMAN MORAN

Chairman MORAN. Good afternoon everyone. The Committee will come to order.

Before we proceed to today's hearing, I would like to take a moment to recognize that last Monday was Memorial Day. It was a different Memorial Day for me and for other Americans than normal, and it was more difficult for us to gather together. But last Monday gave us an opportunity that we should take every day, to pause and remember the brave Americans who gave their lives in defense of our country, and we honor the sacrifices they made to keep us free.

While—let me start by saying that the veterans that we honored on Memorial Day, they served our country, and that peaceful protests are a demonstration of the freedom that our veterans served to safeguard and to protect. While we reject the defacing of our national monuments, I would take another moment to express my gratitude to the National Park Service, its employees and volunteers, who quickly restored our memorials, all of them, but especially those that recognize the service of our men and women, particularly the World War II memorial.

I know that this Committee will continue to further our Nation's pledge—one nation under God, indivisible, with liberty for all. We do that by honoring those who served to make certain we live in that country and we, again, use this Committee as an opportunity to pay our regards and respect to veterans who lost their lives to protect our freedoms.

Today's hearing is on the VA's Fiscal Year 2021 budget request and the supplemental appropriations contained in the CARES Act to respond to the COVID–19 outbreak. We welcome Secretary Wilkie as well as Dr. Richard Stone, Executive in Charge of the Veterans Health Administration; Dr. Paul Lawrence, Under Secretary for Benefits; and Jon Rychalski, Assistant Secretary for Management and Chief Financial Officer.

I appreciate your presence here today and we certainly have done our job to socially distance. Mr. Secretary, despite the distance between you and me and your team, there is nothing other than COVID–19 that causes that to occur, and I look forward to continuing to work closely with you at every opportunity.

I look forward to discussing with you all today how we can work together to improve outcomes for veterans in our country.

I would also like to acknowledge the passing of veterans and VA personnel who lost their lives due to COVID–19. Part of our discussion today is to make certain the VA has every tool it needs to minimize the loss of life during these unprecedented times, and I also want to thank the VA nurses, our doctors, and support staff who work tirelessly to deliver care to veterans during the COVID–19 pandemic.

In addition to serving veterans, the VA has executed its fourth mission, to support the American health care system struggling during this national emergency. This response from these health care professionals has been and continues to be admirable and important and necessary.

While the VA continues to devote resources to suppress the pandemic, veterans will continue to rely on the VA for their needs, such as education, home financing, and transition services. To this end, the pursuit of the well-being of our Nation's veterans must continue unabated.

Between the release of this budget and today's hearing, Congress passed legislation to support Federal agencies responding to the pandemic. Following a supplemental appropriation request from the President, Congress passed the CARES Act, signed into law on March the 27th. CARES provides $19.6 billion for medical services, including telehealth services, equipment, and supplies, personal protective equipment, and emergency room and urgent care. CARES also sets aside $2.2 billion for IT, in order to increase telework capacity and other telehealth needs.

I am interested to learn how the COVID–19 emergency has affected the VA health services and its budget. Retrospectively, did the CARES Act appropriately fund the right places, and prospectively, given the shifting health care demands, does the President's Fiscal Year 2021 budget still address VHA's projected needs?

Released before the COVID–19 emergency, the President's Fiscal Year 2021 budget request includes a proposed increase of $22.8 billion in funding for the VA for a total of $243.4 billion. This represents a 10.2 percent increase above Fiscal Year 2020 enacted levels. I look forward to hearing from you how the proposed budgetary increase will create better outcomes for our Nation's veterans.

I was pleased to see the budget request includes an increase for medical community care as the VA continues to implement the MISSION Act. As we have discussed, many veterans, especially

those in rural States like Kansas, depend upon community care providers for access to timely and quality care.

The MISSION Act was a bipartisan effort to transform veterans' access to community care, it is strongly supported by every veteran service organization, and you have been a champion, Mr. Secretary, to ensure its proper implementation. We all want veterans to receive the care they need through the VA or in their community, and I look forward to discussing the future of the MISSION Act today.

Addressing another of the Committee's health priorities, I appreciate the additional requested funding for mental health and for suicide prevention. Mr. Secretary, I know you share our priority. In January, this Committee unanimously reported the Commander John Scott Hannon Veterans Mental Health Care Improvement Act to provid targeted resources toward research, grants for community partners, and improved coordination between the Department of Defense and the VA to quell the rates of veterans who die by suicide. It is my hope that you will continue working with us to get this bill signed into law soon.

Mr. Secretary, as always, I thank you for being here. I appreciate the difficulty of your job as the Administration works to find a whole government solution to the pandemic. I look forward to hearing your views on the Fiscal Year budget, and I now turn to my colleague and the Ranking Member of this Committee, the Senator from Montana, Senator Tester, for his opening remarks.

OPENING STATEMENT OF SENATOR TESTER

Senator TESTER. Thank you, Chairman Moran, I want to thank you for having this hearing. Before I get into my prepared Statement, I want to say 10 days ago was Memorial Day, and it was a different Memorial Day than I have ever experienced. It gave me an opportunity to think about everything that veterans have given us in this country—the freedom and the promise to live with liberty and justice for all. I think it is appropriate that as we have all said, every day is Veterans Day in this country, because, quite frankly, without the sacrifices, without the job that our military has done over generations, this country would certainly be a different country than it is today.

I hope with all my heart, that we keep in our mind that this country is about liberty, and it is about justice, and it is about liberty and justice for all.

So thank you to the veterans out there, and, Secretary Wilkie, I want to thank you and I want to thank your leadership team for being at the hearing today. Today we get to go over the details of the President's budget request. In the last 4 months, the world has changed, and the VA has changed. More than 106,000 Americans have died, many of them veterans who have returned from wars abroad to die fighting a very different battle here at home.

The VA is our largest integrated health care system in the Nation, and I know the VA has been focused on saving as many veterans' lives as possible, with more than 12,000 veterans having been diagnosed with COVID–19 by the VA. While many are recovering or convalescing, we should never forget that more than 1,270 have died.

As part of this mission, VA has also taken care of non-veterans and has deployed staff and supplies to non-VA facilities like State veterans' nursing homes.

VA's front-line workers and their work force have done an incredible job and deserve more than just a thank-you, because that is not enough for the work that they have done. It has been stellar. We must ensure that the VA has everything it needs to keep the employees that we have safe and take care of our veterans in the process.

Today's hearing is an opportunity for us to take stock of where we are and where we need to be. Mr. Secretary, at the outset of the Nation's response to COVID–19, Congress fulfilled VA's request for nearly $20 billion to support its ability to take care of veterans. We do need a better understanding of how VA has spent those funds and whether unspent dollars will be available to address veterans' needs, whether it be COVID–19 or otherwise, in this next fiscal year.

We also need to ensure that the President's budget request for VA in-house care meets the anticipated health care demands of veterans when looked through the lens of the coronavirus. We also need to know whether private sector providers are prepared to safely administer care to veterans, given the virus' unprecedented effect on American health care. We must anticipate the economic ripple effects of coronavirus on industries across the board, prepare for a potential increase in enrollment and reliance on VA, and evaluate whether the President's budget meets those demands.

We have seen the devastating physical effects that coronavirus has had on those who have contracted the disease, but I think we have also seen large-scale negative psychological impacts such as physical distancing and isolation, the death of loved ones and lack of access to traditional in-person mental health resources.

The VA needs to look to new and innovative approaches to providing mental health care to veterans across the country, such as increased access to telehealth services. As we have seen with this COVID–19 crisis, VA facilities need more space and certainly not less. We need capacity, and we will not get there by short-changing VA's infrastructure.

With veteran unemployment on the rise, it is also critical that the VA communicate what programs we need to support in order to get veterans educated, trained, back to work, and able to provide for their families. One way we help veterans provide for themselves and their families is to ensure their claims are processed timely and accurately. I am truly concerned with the mounting backlog of claims from the COVID–19 pandemic due to deferred and disrupted in-person examinations for veterans, and with how these delays will affect them and their families.

So I look forward to today's hearing, and learn more about how this budget request and the Department's response to COVID–19 has progressed, and I look forward to our conversation. Once again, thank you, Mr. Chairman, for having this hearing, and I want to thank all the witnesses for being here today.

Chairman MORAN. Senator Tester, thank you for joining us. I appreciate the relationship that you and I have, whether we are close

or far apart. Maybe sometimes this works better for us. But I am delighted that you are with us.

I would tell the Secretary and his team that we have almost every member of the Committee present, either here, in person, or remotely. This is a hearing that our Committee members take seriously, and they are participating. While I am pleased that all of our members are here, I also want to acknowledge the presence of Senator Boozman, who chairs the MilCon-VA Appropriations Subcommittee, who has a lot of interest and involvement in your appropriations. So Senator Boozman, thank you especially for joining us with your expertise and interest.

Mr. Secretary, before I introduce you I would say not only thank you for being here but you have been very kind with your time to Senator Tester and I throughout the pandemic. I could not ask for more opportunities to have conversations with you and your team, Dr. Stone and others, and that was very helpful as we explored, and hopefully made suggestions and asked questions that were beneficial to you in fulfilling your duties during this pandemic.

Mr. Secretary, welcome, and please proceed with your testimony.

STATEMENT OF THE HONORABLE ROBERT WILKIE; ACCOMPANIED BY RICHARD STONE; PAUL LAWRENCE; AND JON RYCHALSKI

Secretary WILKIE. Thank you, Mr. Chairman and Senator Tester. You stole the first line. I intended to say, and actually I will say, that in my experience working in this institution, everywhere from the majority leader's office to finishing with Senator Tillis, that I can say that there is no committee of authorization that has been more collaborative or more supportive of the Department that it oversees than this Committee, which is why I do say, with a straight face, it is a pleasure for me to be here.

I also want to pick up on what you and Senator Tester said about the events of Memorial Day. Memorial Day has been part of my life for as long as I can remember. As Senator Tillis says, I was born in khaki diapers and am very proud of it. But this Memorial Day I looked out from the podium at the Quantico National Cemetery and saw three families scattered amongst the thousands of veterans at that cemetery and realized that this really was a different time.

But I will say that we have, at VA, made sure that every obstacle possible was removed, so that on that day of days, those families could be in our cemetery, representing the 1.1 million Americans who have lost their lives since the first shots were fired at Lexington in April of 1775.

Mr. Chairman, you noted that last year we presented the largest budget in the history of this Department. That has now been surpassed by the budget presented to this Committee this year. But I want to say that your support in that budget reflects trust in VA that did not exist 6 years ago. This is not the VA you read about in 2014. Today we are rededicated to Lincoln's vision that we take care of all who have borne the battle and for their families.

Our record of turnaround is something that may be unprecedented in the history of the Federal Government. In just a few short years we have implemented major reforms. Under the MIS-

SION Act we have successfully given veterans real and permanent choice. While some said that the MISSION Act meant the privatization of Veterans Affairs, the numbers show that the opposite has happened.

In the last fiscal year, we completed more than 59.9 million internal episodes of care, a record high. While we were doing that, between June 6th and the declaration of the national emergency, we sent almost 4 million veterans into the private sector to fulfill the MISSION Act's mandate. We implemented critical updates to the Colmery Bill, we took on the new task of caring for thousands of Blue Water Navy veterans, and we continue to make progress in the highly complicated development of the electronic health care record that we will share with the Department of Defense so that people like my father will never be burdened with an 800-page paper record ever again.

Today we continue to implement those reforms even as we cope with, as you and Senator Tester said, a radically new normal that none of us could have foreseen the last time I appeared before this Committee. This epidemic was a shock to health care systems around the planet, but you should be proud, as I am, the thousands of VA employees who put themselves in harm's way to create an indispensable resource, not only for our veterans but for our Nation.

We continue to perform well because we took steps early on that allowed us to keep serving veterans even when there was so much uncertainty. Those steps included the immediate implementation of emergency management procedures in the last week of January, expanding telehealth access and prohibiting visitors to our VA nursing homes and spinal cord injury centers.

Here is where we stand today. As of this week, more than 12,000 veterans nationwide have been diagnosed with the virus, but 80 percent of those veterans are now at home, having recovered. We are caring, as we speak, for 1,200 veterans with the virus, a number that has fallen in the last 2 weeks from 2,200. We have, currently, about 1,100 VA employees who have tested positive, but we estimate that our infection rate, with 330,000 employees in Dr. Stone's department, to be one of the lowest infection rates of any health organization on the planet. It is less than .5 of 1 percent.

Our staffing is stable because we have hired, in the last 7 weeks, 16,000 Americans who have agreed to join us and serve veterans. That means 3,300 registered nurses, 22 CRNAs, 535 physicians, and 202 nurse practitioners who are with us now full-time.

More importantly, we have the lowest rate of infection amongst our nursing home residents, the lowest rate of infection of any system in the country, because early on we took very difficult steps to close off our veterans, sadly, from their families and their friends. Because of that we have 19 veterans in our nursing homes, 19 out of the 7,000, who are infected with the virus. I believe that we have set an example on how to care for our Nation's most vulnerable.

That stability in operations has allowed us to open our doors for the fourth mission, which is to back up the national health care system in times of crisis. We are now in 47 States and territories. By April, we were accepting requests to open dozens of our hos-

pitals to non-veterans across the country. Our expertise in caring for nursing home residents is in the highest demand. We have deployed 294 VA staff to community nursing homes around America, and 330 VA staff have been deployed to help at State veterans' homes.

The crisis, as I mentioned, was not costless for us. COVID has claimed the lives of 32 of our VA families. But in April, April brought us irrefutable evidence that the tide at VA has turned for the better. On the last day of the month we released a survey showing that a record 90 percent of veterans across the country now completely trust VA care. That is a record high and is a record high even in a pandemic.

That is today's VA. It is a learning organization, filled with employees who can turn on a dime to keep veterans and non-veterans safe, even during this time of incredible uncertainty.

Mr. Chairman and Senator Tester, I again thank you for your many courtesies to me and everything you do for our Nation's most deserving.

Chairman MORAN. Mr. Secretary, thank you very much. Let me begin with a handful of questions and then turn to Senator Tester. Committee, we will do this seniority, not knowing the presence of every member at the moment. We will work our way, alternating between Republicans and Democrats by seniority.

Mr. Secretary, can you walk us through why we are seeing a steady growth and increasing funding in both internal VA medical services and community care? Let me use this opportunity to say that I believe that whether the care is provided in the community or provided internal to the VA, both are VA care. They are both part of the Department of Veterans Affairs and they are not separated.

You indicated the hiring of 10,000 medical staff. This, in my mind, could lead toward a greater capability of seeing more people internally within the VA, and maybe result in less people involved in community care.

You have also indicated, to me and Senator Tester over a long period of time, the increasing use of telehealth. How does that then have a consequence on the amount of veterans being seen internal and in community? I mean, I raise this question, in part, because we are being requested in this budget for more money in both categories, internal VA care and community care.

Secretary WILKIE. Mr. Chairman, let me answer the telehealth question first, and I think that is a separate category because it rests on a priority that I gave to this Committee when I had my confirmation hearing.

The two communities in this country who serve the Nation in higher numbers than any other communities are rural Americans and Native Americans, the two populations that are the hardest for us to reach, no matter what the MISSION Act does. But what we have done with telehealth is increase our footprint in rural and Native America.

I will give you an example. In April, we had over 900,000 telehealth encounters. That is an increase of several hundred percent. The reason that is important is at a time of crisis, when those veterans cannot get to our facilities, or they cannot get to their private

sector provider, we have offered them a window to help with their health conditions. I intend to expand our footprint through telehealth into rural and Native America.

On the community care side, I am fully committed to expanding that choice. Even during this time, 60 percent of our normal MISSION Act community care appointments have been carried out. The one thing that we have discovered during this crisis is that many of our veterans are not going into the private sector, and you have seen that all across the country with declining rates not only of wellness visits but visits to the emergency rooms.

That has been the makeup of how we have reacted both to the expansion of MISSION but also the expansion in the confidence that people have in VA. I will let Dr. Stone add some comments about the numbers and budget.

Dr. STONE. Mr. Chairman, the growth in the budget reflects enhanced enrollment—we are anticipating about 30,000 more veterans to be enrolled with us—and enhanced dependence upon the system. As you know, about 80 percent of the veterans that are enrolled with us have other health insurance. They do not get all of their care from us. About 20 percent do get all of their care. But increasing amounts of dependence upon us, as well as the growth in referral to community care.

A small percentage of the increase is due to MISSION Act and the increased requirements of probably not more than 2, 2.5 percent, but Jon will correct me if I am wrong on that number. But it is really dependence upon us and the enrollment. As we come out of this pandemic, we certainly are concerned that financial destabilization of the veteran population may result in even greater dependence upon us, and I will defer to Mr. Rychalski to correct anything I said.

Chairman MORAN. Mr. Rychalski?

Mr. RYCHALSKI. I have no corrections. I would say that from the enrollee health care projection model that we use to predict costs, I think the big cost driver is the reliance that Dr. Stone mentioned. I think more people are taking advantage of the VA. So we are a victim of our own success. I think there are more programs, more benefits, more access, different environment, and frankly people are coming and taking advantage of it.

Chairman MORAN. Is there a way to distinguish between increasing number of veterans accessing care and the cost of care in your calculations of a budget?

Mr. RYCHALSKI. There is. It gets very complicated. As you, I think, know, and Dr. Stone alluded to, I belong to a commercial health care plan and they sort of know that I am going to use their health care plan for all of my health care. The challenge that we have is, you know, we have beneficiaries that have all kinds of Medicare, TRICARE, private insurance, and the challenge for us is predicting how much of the VA they are going to use. You know, we may see an increase in VA because of this, you know, this COVID pandemic, people losing their job, and that is something that we are looking at very closely. But predicting that and sort of knowing is a very difficult thing to sort through.

Chairman MORAN. Thank you all for your responses. Let me turn now to Senator Tester.

Senator TESTER. Thank you. Thank you, Mr. Chairman. I want to thank everybody who has testified. Look, you guys touched on it, and I am going to followup where the Chairman was at. This budget was developed long before we knew there was going to be a pandemic, and, quite frankly, it is a boatload of money, it needs to be right-sized. It does not need to be overly inflated, and it certainly should not be less than you need.

Each one of you talked a second ago about an April increase in the hundreds of percents. You talked about the fact that 80 percent of the folks have health care insurance. I think with unemployment increasing—and you guys talked about this—you are going to see increased dependence upon the VA. We have seen Medicaid enrollment, for example, increase by 2.8 percent February to April, and it is going to increase some more moving forward.

So I think we can anticipate there is going to be more pressure put on the VA, and I think we all can agree on that. I think you have already said that. The question is, does this budget account for that, since it was laid out long before we had the COVID–19 pandemic on our hands.

Secretary WILKIE. Senator, let me—Senator—and Jon can give more details—the one silver lining in what has happened is that when I first started talking to you and talking to the Chairman, we were projecting hundreds of thousands of veterans being infected with this virus. We have mercifully been spared those numbers. Of the 9.5 million veterans we serve, 12,300 have been infected.

What does that mean for the CARES Act and the supplemental funding? That means of the $17.2 billion that the appropriators allocated to us for the CARES Act, we have spent $1.01 billion on medical services. Right now we have more than enough to anticipate the problems that you have just outlined.

Our problems and our emphasis will be on making sure that the claims and that the education programs and the vocational programs are fully up and running so that when we get back to those face-to-face encounters we will be able to provide those veterans with the services they need.

In terms of internal appointments, I do not see it going up much more than it has, because we have reached almost a saturation point in terms of the number of veterans that we have in the system, and the number of veterans across the country is going down.

Jon, did you want to——

Mr. RYCHALSKI. I am sorry. Go ahead, Senator Tester.

Senator TESTER. Well, I would just say go ahead, very quickly, Jon, if you could, because I have some followups.

Mr. RYCHALSKI. Just to confirm what the Secretary said. You know, we did not anticipate this in the budget but we have a lot of flexibility.

The one thing I would like to emphasize, though, where we could really use some help, is we did not get all the right money in all the right places. We do have a real need to move some of that CARES money into VBA—not a large amount—some into NCA, and some flexibility for IT as well. Those are three areas where we are going to be short. Other than that, I think we have adequate flexibility. I think the 2021 budget is adequate, but we did not

know this when we started. It is not all in the right places but it is not bad.

Senator TESTER. So it is your intent that—and this is the question I was going to ask you, and you touched on it, Jon—if your intent is to get authorization to roll any unused CARES Act money into different line items, where you would need money in this budget?

Mr. RYCHALSKI. Yes. In fact, you have given us authority to move some money around within the medical care appropriation, but we would ask for your support in expanding that a bit with—you know, with congressional oversight, to be able to move it to some other areas. I think we are providing weekly execution reports. We are happy to be 100 percent transparent. But we are going to need to move some of that money around to other areas. That is true.

Senator TESTER. That is fine. That is good. That transparency is good, and I want to thank you for that Statement.

So First of all, congratulations. I understand that there have been 16,000 new people hired to the VA in April and May, and if I am wrong you can correct me on that. So congratulations on that. The question is, are these folks in it for the long haul, or are these folks that have retired and came back, that you plan on losing again, or is this really something that we can get our arms around to help solve that vacancy problem?

Secretary WILKIE. Yes, sir. I believe 90 percent are permanent, and that is one of the best news stories that we can have in government.

Senator Tester, I want to followup on something you and I have talked about, and the reason I believe that this funding, the supplemental funding, is so important. I am cognizant that this will boomerang, or can boomerang on us in the fall and the winter. I think the supplemental funding that the Congress has provided us will be our hedge against what could possibly come. We have demonstrated, I think, that we have the procedures in place to ensure that if it does come back we will be ready, and I believe we have the funding to meet that challenge.

Senator TESTER. I appreciate that Statement, Mr. Secretary. Thank you for that. I also say that I do not know what happened in April and May. This is not to what you touched on, but what you said is incredibly important, because if this does boomerang back you have got to be prepared for it. It sounds like you are working in that direction. Thank you.

Whatever you did in April and May, to hire 16,000 people, can you repeat that in June and July? If you do that for a few more quarters we will be in really good shape——

Secretary WILKIE. Yes, sir.

Senator TESTER [continuing]. from an employment standpoint.

Secretary WILKIE. Yes, sir.

Senator TESTER. The last thing, and I will be very quick because if my eyeballs do not deceive me I have got about 50 seconds left. The issues around testing are really important, and you have said that any employee that wants to get tested can get tested. We are not hearing that. We are not hearing that from the folks on the ground. We are still hearing that they are not being tested. Could you shed some light on that as to what the heck is going on?

Secretary WILKIE. Senator, you are exactly right. We are not there yet, although we have tested over 12 percent of our employees. It is our intent to have on-demand testing for all of our employees. We are not there yet. Most of that relates not to the machines that we need. We have the ability to do 60,000 tests a week on our machines. It is the availability of cartridges that go into that from the various vendors and the availability of swabs.

Simply, when we issued the guidance to go to on-demand testing for our employees, we ran out of swabs in a—because of some problems with UPS shipping. That was a national problem with the crashing of UPS systems for a weekend. We have now recovered from that. Right now we have about 60,000 tests available, but we do not have the ability to institute on-demand testing from our employees, but it is our intent to get there.

Senator TESTER. Mr. Secretary, thank you. If I am 3 minutes and 20 seconds over, Mr. Chairman, thanks for not gaveling me down, but I should have been. Sorry.

Secretary WILKIE. Mr. Chairman. may I——

Chairman MORAN. Mr. Secretary.

Secretary WILKIE [continuing]. may I add to that 3 minutes and 30 seconds, because Senator Tester just finished, but this is also addressed to Senator Sullivan and Senator Rounds, and those Senators who have large Native populations.

We have brought into our VA over 2,000 Native Americans for treatment. We have gone into the Native nations, and we are in several of those communities, and it is my intention to expand our footprint there, some of our most vulnerable veterans but also some of our most vulnerable Americans. As Senator Sullivan knows, we have 114 individual Tribal agreements, and it is my intention to expand that so there is no Tribal community that we miss.

But I did not want to go without mentioning our help for the Indian Health Service. Someone criticized me a few days ago for not getting payments. I will worry about that much later. The most important thing is getting those services and that treatment out into Indian country.

Chairman MORAN. Mr. Secretary, thank you. Senator Tester, 4 minutes and 51 seconds over, if you include the Secretary's remarks, and I will try to be more disciplined with my colleagues.

Senator Boozman?

SENATOR JOHN BOOZMAN

Senator BOOZMAN. That is almost twice.

Chairman MORAN. Almost twice.

Senator BOOZMAN. No, we appreciate you, Senator Moran, Mr. Chairman, and Ranking Member Tester for holding this hearing, which is so, so very important. We appreciate you, Secretary Wilkie, and your team for the great job that you do.

This is just a comment. I hope that we can continue to give you the ability to do the hiring process like you are doing it now. I do not know how long it would normally take you to get those people on board, but it would be a long, long time. So again, we appreciate you all working so hard and using the flexibility we have given you.

The Fiscal Year 2021 VHA veterans' health budget request is $90 billion, a $10.8 billion increase from the prior year. If you look at 10 years ago, in Fiscal Year 2011, the budget request for veterans' health then was $52.1 billion. It is really remarkable the growth—to be precise, 73 percent in the last 10 years.

We talked about some of the drivers that were doing that, and I would argue, having been on the Committee in the House and now in the Senate for many years with our distinguished Chairman, veterans health is so much better than it used to be, and we have the confidence now. Lots of people using the system.

We also—is it correct that we have an aging veteran population in a sense with our World War II, our Korea, Vietnam veterans, again, with multiple problems facing, and then the increase in health care costs. So it is a lot of money, but it is something certainly that we are committed to doing. But the good news is I think the thing that is spurring it, as much as anything, is just the confidence that we are seeing in our veterans in continuing to use veterans health care when they could go to Medicare or some other insurance.

Dr. Lawrence, recently we visited, or the staff visited. They were told that the recent suspension of the C&P exams due to COVID that were understandably creating a significant backlog. We have worked so hard to get that down. Can you talk about the plan? What can we do to get that back under control? I think what are we, 116,000 exams, something like that? Is that in the ballpark?

Mr. LAWRENCE. Yes, you are being charitable. This morning it was 119,000. You are correct, sir. On April 2d, when VHA stopped doing C&P exams, we follow their lead, so on April 3d we told our vendors they could no longer do in-person exams. We started conducting ACE exams and using their medical records to do things like fulfill their claim or provide partial benefits. But you are right. The simple math of what took place, and, you know, you all deserve some positive responsibility for that. Through the Blue Water Navy Act, we began to receive a lot of claims in January, and now there are over 125 days. So that is correct.

We have a plan to open following VHA's lead, and that would begin—they opened 20 hospitals. We are opening in that area June 8th. We will startup again C&P exams in certain parts of the country, and we will continue that. The vendors know and they are making phone calls now to schedule it.

We are not happy about the backlog. In November it was 64,000. Our team is very proud of processing claims quickly, so we want to get that right away.

Two things, sir, to answer your question. The first thing was what Mr. Rychalski just said about reprogramming some money, so we will have overtime money to do the claims. The second, we have a piece of legislation, a legislative request in front of you, to allow doctors to conduct C&P exams across borders, and in addition some flexibility for non-doctors to conduct the C&P exams, nurse practitioners and the like. We would ask you to consider that, and that would be one way for us to expand the capacity to work the C&P backlog—work the C&P exams and therefore the backlog.

Senator BOOZMAN. Very quickly, Secretary Wilkie, the fourth mission has been a big success. As a result of that, FEMA, HHS

owes the VA some money. Can you talk quickly about the plan and actually recouping that? What is going on with that? Certainly that would be very helpful to us as we work through the budget.

Secretary WILKIE. Jon might have exact figures, but as you know, statutorily, FEMA and HHS have to reimburse us when we go on missions that they have approved. One thing that I did, though, was I just started calling Governors. We went out ahead of many of those missions because particularly in State veterans' homes there was a crisis, and FEMA has caught up with those requests.

But I will get you figures on how much we are owed so far, unless Jon has new figures.

Mr. RYCHALSKI. I was just going to say, sir, we are tracking it closely. We have worked with FEMA. We have not billed them nor collected anything, but we will be doing so. We can provide you a breakout of that.

Senator BOOZMAN. Thank you, Mr. Chairman.

Chairman MORAN. Senator Brown.

SENATOR SHERROD BROWN

Senator BROWN. Thank you, Mr. Chairman and Mr. Secretary. Thank you and Ranking Member Tester. Thanks for eating up some of my time, Jon. I appreciate that.

We are here to discuss VA's budget and the Department's COVID–19 pandemic responses. Today VA reported 1,200 veterans, 32 VA employee deaths since the start of the pandemic. Our country is in a crisis. People are dying of a disease that continues to spread, particularly among seniors, and especially among the black and brown workers who are keeping our society afloat right now.

We know who essential workers are. They are too often paid too little. One essential worker said to me, "I do not feel essential. I feel expandable. I am not paid very well. My work conditions are not very good," and that is something that all of us on this Committee should think about, especially when they are veterans.

Protesters are in the street now because their government is failing them. It is failing to protect our workers. Not only has it failed to protect black and brown American workers, for generations of people who are supposed to protect everyone it has too often been turned against them.

Peaceful protesters should not be tear-gassed or pelted with rubber bullets so the President can exploit a house of worship, to stage a photo op. They are not terrorists. American cities are not battle spaces. I know that the great majority of veterans, I assume the great majority of VA workers agree with that, and they too are embarrassed when the President disbands peaceful protestors and then brandishes a Bible as a weapon.

On this Committee we honor those who have chosen a life of service. Nothing is more patriotic than upholding the Constitution and exercising our fundamental rights. We need to continue working together to address injustice and inequality to ensure that all Americans are treated fairly.

I have directly heard from student veterans about how this pandemic has affected their GI Bill benefits. Congress worked to provide relief. I am still concerned that the information from VBA is

not reaching all the colleges and universities in a clear format. I urge the Secretary and the staff to work a little harder on that. We need to make sure work-study students still are paid or that when classes are only offered online, GI Bill benefits continue as if classes were in person. Even after we passed legislation to address these issues, my office has heard from veterans in schools.

My First question, Dr. Lawrence. Would you commit to work with my staff, with Anna and Drew on my staff, if we hear of additional concerns about this?

Mr. LAWRENCE. Absolutely.

Senator BROWN. Okay. Thank you. I figured you would say yes, and you have always been cooperative. Thank you.

Mr. Secretary, I appreciate Senator Tester asking about vacancies. I had the same question. We need to continue to drive down the time it takes to hire medical professionals at VA. Can you commit to retain the expedited hiring practices that you have ably scaled up during the crisis?

Secretary WILKIE. Oh, absolutely, and if I need additional authorities I will come to this Committee. I think we have shown, Senator Brown, that the government can work, and we have cut months, almost years off of the hiring process.

One quick thing. One of the incentives that we gave is that we told people if you joined us you can stay in your hometown or in your home State should you so desire. I think that is a huge incentive.

Senator BROWN. That is very important. I wanted to take this opportunity to urge you to find a way to negotiate in good faith with the VA unions. I and veterans know they get better care, and employees know their concerns are addressed where union representation is at the table. We know that workers are more productive and they are better treated.

Dr. Stone, Dr. Lawrence, have you reviewed the white paper released by the National Veterans Legal Services Program and the Jerome Frank Legal Service Organization at Yale Law School. Veterans who were stationed in Guam for a decade in the 1960's and 1970's were likely exposed to dioxin-containing herbicide agents, including Agent Orange. Have you looked at that paper and do you agree with the assessment? For Dr. Stone and Dr. Lawrence.

Mr. LAWRENCE. Sir, let me go first. Yes, sir. We reviewed the paper and I believe we responded to a letter to you all about, you know, the inability of us to find the use of the dioxin in that area. I know it was a very complicated paper that required analysis from our team. I am happy to discuss it more with you, but yes, it has been reviewed.

Senator BROWN. Okay, thank you. Dr. Stone, do you want to add anything?

Dr. STONE. Sir, I have reviewed the paper and I agree with Dr. Lawrence. It is very complex in its process and we look forward to coming to resolution on it.

Senator BROWN. Okay. It is important that the VA always stand—as you know, always stand with veterans and Agent Orange. We are sometimes slow to that. With burn pits and now with this study it is important always that we come down on the side of veterans.

Last comment, Secretary Wilkie and Dr. Stone. The VA has made a major shift toward telehealth to decrease possible spread of COVID–19. When we passed the CARES Act we included specific funding to increase veterans' access to internet and telehealth. Some areas of Ohio are rural. Many of the Senators on this Committee have even more rural areas than I do. They do not have great access to broadband. This is especially important as veterans rely more heavily on telehealth for the foreseeable future.

I hope you will share—my time is up, but please share with the Committee at some point what steps VA, or with my staff, what steps VA has taken to enter into contracts to expand broadband and telehealth services for our veterans.

Thank you, Mr. Chairman. If you would just—you can answer that question in writing, or if you want to take the time now.

Secretary WILKIE. We will. It is a priority for us, particular, as you mentioned, in rural America.

I did want to say something about your opening comment about—I believe you mentioned gender disparities. We are in an interesting position at VA. Forty-nine percent of eligible male veterans are in our system. I can say to this Committee today that 42 percent of all eligible female veterans are now in the VA system. Dr. Stone has just hired an assistant, special assistant, to monitor those issues, any disparities, and report directly to him. I think we are the only health care system in the country to monitor gender and racial disparities in terms of health care and health care outcomes.

So we are in the lead, and I think for many of those communities the health care outcomes are much better within our system than they are in the private sector. So I take your point to heart.

Senator BROWN. Thank you, Mr. Secretary. Thank you, Chairman Moran.

Chairman MORAN. Senator Cassidy. You are welcome.

SENATOR BILL CASSIDY

Senator CASSIDY. Thank you all. Thank you for your good service and thank you in New Orleans, which had a lot of COVID. You all did a lot of work to kind of mobilize resources. I really appreciate that.

A couple of things. I have heard—again, as a physician I get these phone calls from physicians all over the country. Now one thing that has been said that in the referral to outside specialists for different aspects of care the intensity of the care is greater than it would be if it were given in the VA, that every test is done that is imaginable, and some of which you would not think would be indicated. Maybe you cannot establish that they are not, but they ordinarily would not be done in a more well-run system.

We are speaking not just for the VA in general but we are also speaking for specific facilities, because you want to have a kind of a spectrum of that. Dr. Stone, I think you have been flagged for this.

Dr. STONE. Yes, sir. We authorize standard episodes of care in which we define the scope of services to be done. But we do find a greater utilization of services out in the commercial space than we do——

Senator CASSIDY. Now that assumes, Dr. Stone, just because I have limited time, if you do have greater utilization of services, either there is an underutilization within the VA or an over on the side. Now I will just say, as a doc, if you do too much, bad things happen. It is not benign to do something which is not indicated. On the other hand, it should be done if indicated.

So do you have a sense of inside versus outside as to the relative weight of that?

Dr. STONE. Yes, and, sir, that is why we designed the Community Care Program to be highly integrated with the VA at the center and the primary care clinician at the center of that, to make decisions in the best interest of the veteran, and to work with the veteran for how to proceed. We fine, in some very simple areas, like physical therapy, dramatically higher uses in the commercial space that is done within VA.

Senator CASSIDY. But begging the question, is it appropriate increased intensity, or not?

Dr. STONE. Not always.

Senator CASSIDY. So is there—I presume then that you all are taking measures, because that is one, expensive, but two, it is also perhaps contraindicated, which is more important.

Dr. STONE. We are, and that is the beauty of the health information exchange, which allows us to utilize and to integrate health care information systems for the veteran so that there is not repetitive work being done, and we have full visibility.

Senator CASSIDY. Is it possible that you could give this Committee a report on a per-institution basis? The Dartmouth study suggests that it is regional, or even State, or even community located in which you have increased intensity of certain services. I think the individual members of the Committee would like to know how the VAs in their bailiwick, if you will, are responding to this challenge.

Dr. STONE. We would be happy to work with your staff and the Committee staff to really work through that request.

Senator CASSIDY. Let me ask, Mr. Secretary, you mentioned the success in hiring new people, but I was recently told it can take as long as 6 months for someone to be offered a position for them to actually be onboarded and to be seeing patients. Any comments on that?

Secretary WILKIE. Senator, before Dr. Stone answers that, as a physician might answer that, we have been able to cut through most of the Federal flotsam and jetsam when it comes to hiring people. I have shaved off weeks and months out of the hiring process. When people apply, that hiring application goes straight to the medical center or to the department that would be hiring that person. The onboarding is done quickly. So we have cut down years, months into weeks, and I do not know that anyone right now is experiencing that 6-month delay. Now there may be one or two specialties that might, but Dr. Stone can answer that.

Dr. STONE. Sir, it was not uncommon for us to take 6 months to bring a clinician on, mainly because of the prime source of verification of their education. With the help of Office of Personnel Management we have cut that down to 7 days now, that if you apply today, in 7 days we will have you at work.

Senator CASSIDY. Really?

Secretary WILKIE. We have hired almost 600 physicians just in the last 6 weeks.

Senator CASSIDY. I have got 36 seconds left. Let me ask you a 4-minute question. During the COVID, coronavirus crisis we have been using more tele mental health and telehealth services. To what degree can we continue to use those tele mental health? Have you found them as effective as traditional mental health services?

Secretary WILKIE. We certainly have, and I think this is the wave of the future, particularly for mental health. In addition to what we have provided, we have now entered into agreements with—I will give you an example—Walmart. Senator Tillis knows, I cut the ribbon on a Walmart Veterans Health Clinic that exists behind the pharmacy wall, where a veteran can come in and talk to a mental health provider—this is in Asheboro, North Carolina—anywhere in the country.

This is the wave of the future. It prevents veterans from having to experience the pressures of a large clinical setting. It takes the pressure off of their families. I expect it to grow. I think the one benefit of this epidemic, it has allowed us to stress the test.

I will finish by saying—I am going to make a Louisiana comment. My grandmother is watching, in New Orleans. She was born in the middle of the Spanish Flu at the early part of the 20th century. She is still in New Orleans. She survived this one. So that tells you the resilience of the Crescent City.

Senator CASSIDY. Thank you. I yield back.

Chairman MORAN. Senator Blumenthal.

SENATOR RICHARD BLUMENTHAL

Senator BLUMENTHAL. Thank you, Mr. Chairman. Thank you all for being here. Thanks for your service. I saw a report, I think this morning, in the Military Times, that the number of active COVID–19 cases at VA medical centers nationwide has risen by more than 7 percent in the last 5 days. That is a pretty alarming turnaround, in contrast——

Secretary WILKIE. I can answer that. The system—the accounting system was down for several days. But overall, 9.5 million veterans that we serve, we have had 12,300 infections. Of those 12,300 infections, we have less than 1,500 active infections. I think there is no health care system in the country that has been able to keep those numbers down as we have. I think we did it because we acted early. We were acting in February.

Senator BLUMENTHAL. My question to you, though, is the trend. What has been the trend over the last 5 days? Are you saying that the Military Times was in error?

Secretary WILKIE. I am saying their interpretation was in error.

Senator BLUMENTHAL. Well, you are saying they were in error.

Secretary WILKIE. I said their interpretation was in error.

Senator BLUMENTHAL. What are the numbers?

Secretary WILKIE. I gave you the overall numbers.

Dr. STONE. Sir, if I might add to this, I would ask you, Senator, to consider two things, one, the number of cases, and second, how many are hospitalized. Our hospitalization numbers are stable and are not increasing. I think as we increase testing, and we are doing

3,000 to 4,000 tests a day in veterans, you are going to get numbers going up. It is just like in each of your States, that as you penetrate with——

Senator BLUMENTHAL. Well, that is an explanation, but the numbers are showing an increase. Correct?

Dr. STONE. The actual number is showing an increase, but not in hospitalizations. Hospitalizations——

Senator BLUMENTHAL. It is an increase in the number of active cases. I understand hospitalizations are different from active cases.

Secretary WILKIE. Yes, and most of those cases are at home.

Senator BLUMENTHAL. At home?

Secretary WILKIE. Because they do not require——

Senator BLUMENTHAL. Well, that may be true——

Secretary WILKIE [continuing]. they do not require——

Senator BLUMENTHAL [continuing]. I am asking you for numbers.

Secretary WILKIE. Well, I just gave you the numbers.

Senator BLUMENTHAL. I just want to make sure that I understand. The trend is up by around 7 percent of active coronavirus cases. The Military Times was correct in that report.

Secretary WILKIE. The trend—Look. The interpretation is that there is an explosion.

Senator BLUMENTHAL. Let me move on to another topic because I am limited in terms of time. My understanding is that you have spent only—you have obligated only about $2 billion out of the $19.6 billion that has been provided under the CARES Act. Why so small a percentage of the funding obligated?

Secretary WILKIE. Well, because mercifully the original projections that I discussed with the Chairman and Senator Tester of several hundred thousand infections did not play out. Those were the projections we were looking at at the beginning of this.

Senator BLUMENTHAL. So you do not need the money?

Secretary WILKIE. I also mentioned earlier, Senator, that I am standing by for a rebound. We do not know what is going to happen in the fall and winter.

Senator BLUMENTHAL. So if that 7 percent trend that I just mentioned continues, you might need the money more than you do now?

Secretary WILKIE. Well, I think with the rebound you would see people who have had no contact with the virus be susceptible to it in the fall and the winter.

Senator BLUMENTHAL. Let me ask you, with respect to PPE, how many—and this is relevant to the potential rebound—how many weeks of supplies do you have now in PPE?

Secretary WILKIE. We have multiple months of supply of PPE.

Senator BLUMENTHAL. Multiple months?

Secretary WILKIE. Yes.

Senator BLUMENTHAL. So you have more than ample personal protective equipment.

Secretary WILKIE. If I can add, the Chairman and I have talked, and so has Senator Tester. We are setting up a system that is something that you were familiar with in your Marine Corps days. The Marine Corps and Navy had supply depots all over the country—spare parts, technicians. We are doing that with our PPE and our medicines. I think this is our hedge for the future, so that we

will not be susceptible to a disruption in the supply chain. So I have adopted the models that I saw as a young naval officer, and we are preparing by stocking up.

The other thing I would say is that we never fell below 2 weeks of supplies during this crisis.

Senator BLUMENTHAL. I have one last question. I have many questions. Some I will submit in writing, but one more question I want to ask you here. I introduced a bill last year that was supposed by 18 veteran service organizations to remove the 1-year manifestation period for three illnesses linked to Agent Orange, and I would like your support for that bill, 50 years after the veterans suffered the harms that are still affected.

Secretary WILKIE. Well, I certainly—as the son of a combat soldier from Vietnam I understand it probably as well as any dependent. Dr. Stone and I will be reviewing that, as well as several other studies that are tangential to your legislation, in the coming weeks.

Senator BLUMENTHAL. While you are reviewing that, maybe you could also indicate why you have not categorized as a presumptive disability three—several conditions that are classified by the National Academy of Sciences in that regard. I know that ordinarily you follow their recommendations. In 2016, the National Academies recommended adding four new conditions to the Agent Orange presumptive disability list, including bladder cancer, hypothyroidism, hypertension, and Parkinson-like symptoms. Despite that scientific backing, you have not added those conditions.

Dr. STONE. Sir, we and the Secretary have spoken previously about this, and we are waiting for these two additional studies to finish, that are broad studies of death rates as well as the health status of the Vietnam veteran before we come to agreement on that. We have talked to the National Academy of Sciences and looked at the statistical variance that they have, and frankly, I am not as convinced as the National Academy of Sciences is. But we will defer to those two studies and then make recommendations to the Secretary.

Secretary WILKIE. Mr. Chairman, if you would indulge me to finish the original question Senator Blumenthal asked about the 7 percent increase and why I was questioning the interpretation. We have 9.5 million veterans in our system. We have had 12,300 infected, mercifully, an incredibly low number. Of those 12,300, well over 9,000 have completely recovered. So a 7 percent increase—and why I was challenging the interpretation—sounds like there has been an explosion in terms of the number of veterans infected. It has been mercifully low if you look at the entirety of the community we serve.

Senator BLUMENTHAL. My time has expired. I thank you, Mr. Chairman.

Chairman MORAN. You are one of my Ranking Members, as is Senator Tester, and you almost got as much overtime as he did.

Senator Rounds?

SENATOR MIKE ROUNDS

Senator BLUMENTHAL. Thank you.

Senator ROUNDS. Thank you, Mr. Chairman. Mr. Secretary, gentlemen, thank you all for your service to our country.

Mr. Secretary, in a call we had with you just a few weeks ago you were confident that any overdue provider claims were old Choice-era claims, but earlier this week, in preparation for this hearing, leaders from your department told members' staff that there are aged MISSION Act claims among the VA's current backlog. This does line up with your written testimony today, page six of your testimony, in which you have indicated, and I will quote, "The VA realizes it needs to do a better job of paying claims from community providers." It is certainly reflective of what my experience is and what I continue to hear from my providers in South Dakota.

Looking at your request for $18.5 billion for community care for Fiscal Year 2021, what I would like to know is, is this enough to make sure your department can do what needs to be done to get our community providers paid in the time that the law currently requires? Just as an example, is this enough money to get the eCams up and running at 100 percent capacity? I think according to discussions with staff earlier this week it is running at about 33 percent capacity. Our expectation, based on a February discussion, was that it would be up and running by about May 4th or so. So we have got a ways to go yet.

Is this enough money to clear your backlog of the 2 million claims, and help the VAs transition out of the direct payer role altogether?

Secretary WILKIE. Before Dr. Stone answers the way forward I will say, and I have been in South Dakota twice in the last 6 months, since MISSION kicked in on June 6th of last year we have processed 22 million claims and disbursed $6.9 billion. I can say that with the coming of new management to our regions right now the number is at 57 percent of all claims are now paid within 7 days. That still means we have a backlog, but it is moving in the right direction.

Dr. STONE. Senator, the last time you and I talked about this I had between 3.2 and 3.4 million claims in backlog. That number is now down to 1.9 million, and we disbursed over $1.3 billion in payments last month, in the month of May. I think we are going in the right direction. eCams has not come on board at the rapidity at which we wanted, although it is running well. What we are looking for is auto-adjudication, where it, on an automatic basis, adjudicates a claim. That, you are exactly correct, it's not at the level it should be. I have been reassured by Dr. Mathews and her team, who are running Community Care that in the next month we will take a dramatic upturn in the amount of auto-adjudication that is driving this down.

Now the first question you asked was, is $18 billion going to be enough? It looks like it. It looks like even with the growth in the dependents and the unknown that we have as we go into a potential second wave, or even third wave of this pandemic, we will be Ok with that number.

So I am confident in that number. What I am still not happy with is the amount of backlog claims. We must be a good partner to every provider or we are not going to keep the 880,000 providers who have pledged their commitment to Americans veterans.

Senator ROUNDS. Thank you, and I think that is really the crux of it for us, is if we are not paying these providers in a timely fashion. A lot of them do not have real deep pockets, and if they cannot get paid to continue to pay their bills, then at some point—and so far none of them have declined the veterans, but we most certainly do not want to get them to the position where they feel that they may.

Dr. STONE. Senator, they have not, and we are keenly aware that the American health care systems in the private space are losing $50 billion each year, and we have worked really hard to make sure that we can do our part to maintain their liquidity.

Senator ROUNDS. Great. Thank you.

Mr. Secretary, can you give me a walk-through of the decision to decrease your requested funding for the VA's Rural Health Initiative this year by 10 percent, from $300 million in Fiscal Year 2020 to $270 million in Fiscal Year 2021? It seems that with your emphasis—and I know you have been to South Dakota twice and you have talked about what we need to do to work with IHS in our rural areas. But to see that decrease kind of caught me by surprise.

Secretary WILKIE. I will go back and look. I think it is because of the emphasis on telehealth, which has cut down on costs. But I will give you a line-by-line breakdown of why that happened.

I would also add—and this is a parochial matter for you—I was on KELO yesterday, and I wanted you to know that I renewed the commitment to Hot Springs on South Dakota television, and my staff has been in contact with your staff to make sure that when we deal with that record of decision it is not only airtight, it is also in line with the legislation that you put in the appropriations bill.

Senator ROUNDS. Thank you. Thank you, Mr. Chairman.

Chairman MORAN. Senator Rounds, thank you very much. I meant to mention after Senator Blumenthal's questions that this Committee will have a hearing next Tuesday. He was asking the Secretary—Senator Blumenthal was asking the Secretary about PPE. Our Committee will meet next Tuesday afternoon to have a hearing. The title of the—the subject is "Building a More Resilient VA Supply Chain." So we are going to spend some more time with the Department in regard to this topic.

Now Senator Hirono.

SENATOR MAZIE HIRONO

Senator HIRONO. Thank you very much, Mr. Chairman. What is happening in our country right now is a tremendous acknowledgment of the disparities that have existed in our country for far too long. The pandemic has further exposed the disproportionate access people of color have to critical services, like health care, housing, education, social supports, and protests are happening all over the world, in all of our country, including, of course, in Hawaii, in response to violence against black Americans.

We are at a time in our country when we cannot just go back to doing things as usual, and if ever there was a time to have some kind of reckoning to move us forward, this is it.

When the top leadership of our agencies does not reflect the people they serve, that can have real lasting consequences. So, Mr. Secretary, I would like to ask you, would you agree that diversity

in those who are making decisions that impact the lives of all the diverse group of veterans that you serve, is not diversity in leadership a good thing in order to provide truly equitable services to veterans?

Secretary WILKIE. Senator, I will be careful in my answer. I grew up in this world. I think you will find that the Armed Forces of the United States have been the great leveler when it comes to equal treatment. I have surrounded myself with people who have the same experiences. Everyone at this table has served in uniform. We understand the culture and we speak the language. My deputy, she graduated from—she graduated from the United States Air Force Academy. Our Assistant Secretary for Legislative Affairs, who is sitting behind me, I actually served under in the Air Force.

We have one goal. It does not matter where we come from, we have all served. I think for us, at VA, that is the most important thing. I would also add what I said earlier. We are the only health care system, Senator—and you and I have talked about this—we follow gender disparities. We follow racial disparities. We have now brought up, just in the last few years, the percentage of veterans who are women to 42 percent. The percentage of veterans, eligible veterans, who are male are 49 percent. So we are moving up.

Just a few years ago there were only a few, less than 200,000 women in the system. Today there are 500,000. So I think we have——

Senator HIRONO. I acknowledge that. What I am talking about are the people who are making decisions on behalf of the diverse group of veterans that you now have, and many of them are women. We are already acknowledging that they may have different kinds of health care and other kinds of needs, and therefore you are programmatically seeking to address those. But it is really the people who are making decisions.

Let's face it. I am not disparaging anybody who is in the military, by the way, and there should be an acknowledgment that we all have implicit bias. No matter how fair we may all think we are, that unless you walk in the shoes of somebody else then it is—it is not the kind of thing where we can, "Oh yes, I know what you feel. I know what you are thinking."

Secretary WILKIE. My, my——

Senator HIRONO. So this is why I would say, diversity in leadership is important.

I do have a question for you before I run out of time.

Secretary WILKIE. I will just say my deputy, she served 30 years in the Air Force, and I think that is a testament to how far VA has advanced along the lines, that you——

Senator HIRONO. I am all for women in decisionmaking, but we all know within the military there are still major issues relating to sexual assault and sexual harassment, but that is a whole other matter. We also know there are disparities within the VA, and I am glad that you acknowledge it and you will, I hope, do something about it.

But do you do implicit bias training within your leadership group in the VA?

Secretary WILKIE. Yes, Senator, we do.

Senator HIRONO. Good to know. For years, I have brought up the Advanced Leeward Outpatient Health Care Access Project at hearings and meetings with VA leadership. The project was scheduled to be completed by Fiscal Year 2020, but has encountered multiple delays. Earlier this year, the VA said that this lease award was expected by mid-May, but in the recent weeks we have learned that that has been delayed due to COVID–19. Now a lease award is not expected until mid-August, and the project is not expected to be completed until spring of 2023.

You can see where the veterans are very concerned that this project keeps being delayed. Can you explain to me what exactly is causing yet another delay and how VA is working to address it and provide a—could you provide a detailed timeline for the ALOHA project so that I can let the veterans in Hawaii know when they can expect this facility to be built?

Secretary WILKIE. Yes, Senator, and you know I have been in Hawaii several times, and the ALOHA Clinic is a classic example of what happens when there are too many layers of Federal bureaucracy. Some not attached to the VA gets involved in construction projects. This is a problem that I will bring to the Chairman, and I think I have mentioned it to Senator Tester as well. The way CBO scores these projects is not realistic. The other thing that I will bring to the Chairman is that for projects like the ALOHA Clinic in Hawaii, which have stopped and started because of CBO and GSA bureaucracy, we want to give more flexibility to the Department and to the leaders on the ground to be able to engage in these contracts, contracts that reflect the situation in Hawaii, and not a one size fits all.

So I take your point. You are absolutely right, and we are working on providing this Committee with hopefully some legislative solutions so what happens in Hawaii does not happen again.

Senator HIRONO. Thank you so much for acknowledging that, and of course things are much more expensive in Hawaii, and one size fits all where the costs are not fixed do not do it for us in Hawaii. So I will do whatever I can to assist you, Mr. Secretary.

I am glad that one of the——

Chairman MORAN. Senator, your time has expired.

Senator HIRONO. Oh, I am sorry. I will send more questions for the record. Thank you, Mr. Secretary.

Chairman MORAN. Thank you, Senator Hirono. The announcement about the vote has been delayed 10 minutes, so it is now at 4:40. So we have—I do not know what we have.

Senator Tillis?

SENATOR THOM TILLIS

Senator TILLIS. Just enough time for my round.

Chairman MORAN. Apparently you are the lucky one.

Senator TILLIS. Thank you, Mr. Chairman. Senator Tester, it is great to see you have found your flat top again. It is a good luck.

Mr. Secretary and for all the witnesses, I want to go back on—I have completed 45 telephone town halls, updating people in North Carolina on COVID, and one thing it has required me to do is to take a look at the numbers and not view any one number in a vacuum. I am sure that you guys are taking a look at any in-

crease in cases, you are adjusting that, you are looking at the rate of doubling, you are looking at how you adjust that for the rate of testing, and those numbers.

So Dr. Stone, in your opinion, do you believe—because this hearing people could leave saying that the VA admitted there is a 7 percent spike. But are you looking at all those numbers, and in that context doing it as a manageable number that is within your expectations?

Dr. STONE. Yes, sir. Early in this we were dealing with very rapid doubling rates. We are now dealing—your State has had gradually increasing numbers, but with a doubling rate that extends out to between 30 and 40 days.

Senator TILLIS. Right, and early in the crisis we were in 5-and 10-day increments.

Dr. STONE. We were in 1-and 3-day doublings. So yes, sir.

Senator TILLIS. So I just wanted to level-set that. Before anyone takes any one number they really need to understand the numbers if they want to do it justice——

Dr. STONE. Yes, sir, and——

Senator TILLIS [continuing]. on the trends. Because clearly you would be surging if you had a concern.

Secretary WILKIE. Senator Tillis, and I was not trying to be disrespectful, but—and you know that I went into the law because I could not do math.

Senator TILLIS. Yep.

Secretary WILKIE. But when we have an infection rate that is as low as ours, a 7 percent increase is in the tens or maybe, at most, the dozens. That does not mean it is not serious, but it is not a crisis. I think we have shown since this began that we have been able to manage, and our veterans have responded. We have set out well over 50 million individual communications to veterans and families. We have warned them of what was out there. We have given them instructions and they have responded magnificently, which is why I think the numbers are as low as they are.

Senator TILLIS. Thank you. Jon, you mentioned the need for reprogramming some of the additional dollars. I think you have been good stewards. I think you would have spent all $18 billion if you thought it was necessary. You are demonstrating good stewardship on the money that was allocated under the CARES Act.

I would expect—I know IT is something that you mentioned—I would expect that as you scale up telehealth, as maybe you scale up capacity for some of the underlying information systems, that those are some areas where you need flexibility to deploy resources. We need to make sure that we get that information.

I also think that—I am looking ahead to a surge. If we take a look at the breakdown of patients, particularly acute cases and deaths, it is clearly in congregate care facilities and populations where we have higher risk categories, over age 65, underlying health conditions, et cetera.

We are going to have another wave. The question is how many therapeutics do we have and what have we learned in terms of protocols to reduce the spread. But also I think, and particularly among the senior veteran populations and congregate care facilities writ large, we should already be creating a mentality for a posture

that we take before we hear of the first case in November or December. Are you all taking those steps and trying to inculcate that as a part of your culture?

Secretary WILKIE. So we have, and the nursing home community is the example. We serve a little under 8,000 veterans in 134 nursing homes. We put in emergency protocols very early on in this. We test everyone in the nursing home. We also test all of the employees. We stopped visitors and families—a very difficult decision, because more than half of those veterans are from Korea and World War II.

Senator TILLIS. Yes, and Secretary Wilkie, because I want to ask an open-ended question and finish before the red light. I think it is just important. You know how heartbreaking it is when you want to go visit someone in these facilities. I think if we set the expectation now, so that they just know that that is standard operating practice, it is going to be easier to manage that and make it less likely that we see anything approaching it. I do not believe we will see anything approaching what we have in this wave.

The last question, and it is really maybe something for you all to think about. I have had this discussion with DoD. As you are looking at deadlines and you are looking at other requirements Congress has placed on you, that you could rightfully assert that maybe you need a little bit more time to get certain things done—it could be projects, it could be reports, it could be any number of other things-—I hope that you will report back to us and let us know, to the extent that that is going to require statutory action. I think you would have a rational basis for knowing what those are.

Offline we will talk about the electronic health record implementation. I know it was delayed somewhat. I would be interested in knowing whether or not there are resources that we could put in so that we can continue it maybe through tele-implementation and a number of other things. I know the platform providers implement it in the private sector.

Thank you.

Chairman MORAN. Thank you, Senator Tillis. Senator Manchin.

SENATOR JOE MANCHIN

Senator MANCHIN. Thank you, Mr. Chairman. I thank all of you for being here before us today.

First of all, I am just going to take a moment to thank all of the Veterans Affairs employees that we have in our State, and that you have around the country, because they have been stalwarts. They have been on the front line there and they have done a great job. They really have.

My concern has been, and I think Secretary Wilkie and I spoke about this, the testing. Veterans are having a hard time. They are confused about the testing. They are told they have to pay for it, and that it has been, you know, pre-approved, and going through all the red tape. Have you been able, Dr. Stone, maybe to work through that, that clarifies this for them, to make sure that our veterans can get tested if needed?

Dr. STONE. Sir, I appreciate your advocacy for this, and you and I have talked about it. Where we are having trouble is this drive-

through testing. When the drive-through testing is being done by somebody not enrolled in our system is where we are having trouble with it. What we would like to get, and what we have reached out to do is try and look at every drive-through testing, any place we can find it, and try to enroll those health care systems in this.

Unfortunately, some of them——

Senator MANCHIN. Is there something we can do to help you? Is there anything that we can do legislatively, or something through our office officially to help you?

Dr. STONE. Yes. I think that we will work with your staff on it. Right now Community Care believed that they were well on their way to working their way through this, to make sure that there was no bill sent out to any veteran. I can reassure you that within our system there have been no bills sent out for COVID testing, and if there is we will reconcile it.

Senator MANCHIN. Okay. Well also—and, Mr. Chairman, you have said that the PPE, we are going to be doing that next week?

Chairman MORAN. I am sorry. Yes.

Senator MANCHIN. The PPE? Because I know—we have put nearly $20 billion in that in order to train, so we will get an accounting. There is no use for me to ask that question if you are going to get back into that next week.

Chairman MORAN. We will.

Senator MANCHIN. Sir, and Dr. Stone, on the VA in Clarksburg, 2 years. The rumors going around now are just unbelievable in the local circles, about even the person of interest maybe still working, or being employed, or coming back as a contractor. Have you been——

Dr. STONE. Sir, I can reassure you, as of a discussion yesterday, that is absolutely untrue.

Senator MANCHIN. Well, I think it is too. It is a vicious rumor going around that is hurting an awful lot of families. But the most important thing is the 2-years. Do you see any end in sight?

Dr. STONE. Sir, the answer to that question has to be done by the IG and the Justice Department.

Secretary WILKIE. Senator, I have expressed my frustration with this. You and I talked, and Senator Capito was on the phone. This investigation began before I was Secretary.

Senator MANCHIN. Right.

Secretary WILKIE. That is a disservice to the people of West Virginia.

Senator MANCHIN. It is just—I cannot explain it. I mean, you can imagine what the families are going through. Why would you put anybody through this? I know you are not intentionally—I know that, Secretary Wilkie, you could not believe either, the insensitivity of what is going on. But we have got to get an answer. I am going to go, I think, to Attorney General Barr. I have got to go to Attorney General Barr. I have gone there before but now it is urgent now, 2 years. Now with these rumors starting to creep up, you understand the whole uncertainty of what is going on and these people being left in limbo like that. It is just-——

Secretary WILKIE. Sir, this is a disservice to every veteran in that community, and as you know, this is a small community.

These employees have done a great job of cooperating every step of the way, and we look forward to resolution.

Senator MANCHIN. Anything you can do to help us we appreciate.

Secretary WILKIE. Thank you.

Senator MANCHIN. Thank you.

Chairman MORAN. The next senator—I think we only have Senator Sinema left, and she is to call in at 4:40, which is now. Senator Sinema, are you available?

[Pause.]

Chairman MORAN. Let me ask a question then, Mr. Secretary, which I had intended to ask at the end of the hearing. I was caught—my attention was caught by the two questions by both a Republican and Democrat about testing and about the 7 percent increase. I want to make sure I understand what that reflects.

My assumption is that as more people are tested we are going to see more positive numbers. Perhaps this is a question for Dr. Stone, but what is it that we should—what-—if something happens, what should we be concerned about? What is the standard by which it raises a concern or a significant challenge for the VA, based upon its numbers, in caring for veterans?

Dr. STONE. So what you should be concerned about in a community is the prevalence of the disease. We began this whole thing when we built the budget for this, anticipating that 2 to 3 percent of the population would be infected. We are dealing with a fraction of that, frankly. We are dealing with a tenth of that.

Second, what VA must be concerned about is the ability to take care of sick people. About 20 percent of the positive are really sick, and do we have enough beds, do we have enough equipment, do we have enough personnel to care for them? Hence, the reconfiguration of the VA's delivery system to grow by almost 4,000 beds as we went through this, and the hiring of massive numbers of people, and the reconfiguration and retraining of ambulatory nurses and providers to provide care and support for the less ill, so our critical care providers can care for that.

The VA is well positioned to remain the backstop of the American health care system and to fulfill the mission that the Secretary gave us and that you all expect of us. At this time, as we enter this, I am at 37 percent on our ICU occupancy, meaning that two-thirds of our ICU beds are now empty today, across the system. Second, we are at about 53 percent occupancy on our medical-surgical beds. Those are the key questions that you want to know as we walk through.

Now what we have seen across this Nation is this slow background of cases, not in rapid spikes like we saw earlier in the disease, in late February and early March, where we saw these huge spikes. We have seen this slow background. We anticipate having about 600 patients as inpatients for COVID right through the fall.

The question will be, will this repeat the activity of summer to fall 1918, where wave two is much more malignant, a much tougher disease, so that wave two really resulted in dramatic deaths in late 1918 and in the early winter of 1919, January, February.

Chairman MORAN. Dr. Stone, what does medical scientific evidence have to say about that at this point? Anything?

Dr. STONE. At this time we have no idea. But what I think your expectation of us should be, and I know what the Secretary's expectation of me and my leaders is to build a system that can appropriately backstop.

Secretary WILKIE. Mr. Chairman, I mentioned that we started preparing for this early on. We have done things like purchase mobile hospitals that we did not have to deploy but they are ready. I also mentioned the creation of a military-like depot system.

The other part of that is that I signed a memorandum of agreement with the Defense Logistics Agency so that we are joined at the hip with them and their computerized systems so that VA is no longer the ad hoc system that it has been. The year that I became Secretary there were over 4 million credit card transactions, buying everything from tongue depressors to radiological equipment. These reforms go a long way to eliminating that and making us better prepared for what may come in the fall.

Chairman MORAN. Thank you, Mr. Secretary. Thank you, Dr. Stone. I am going to turn to Senator Tester for a second question, and then Senator Sinema is joining us now.

Senator Tester?

Senator TESTER. Thank you, Mr. Chairman. A couple of things, and these could be really quick, guys. But on masks I know there have been multiple versions of guidances put out on masks about how they are to be used, if they are to be reused, all that stuff. Have you guys been able to put anything in writing, to direct the staff so they know what the expectations are on the N95s?

Dr. STONE. Yes, sir. The guidance you reflect occurred on the 7th of April, and then when we went to a crisis mode, and then we went to contingency mode on the 14th or 15th of April, and I will get you the exact date. So it was only for 1 week in this that we went to crisis mode on utilization, and we remain at the guidance that was given on the 14th or 15th of April, which provides one mask per day, per patient that needs an N95, which is those employees in direct contact with COVID patients.

Senator TESTER. Okay. That is good. I mean, I think that there is some confusion out there, but if you guys got it out and you field it, that information is flowed to the proper sources, that is all you can ask for.

Electronic health records. I do not really want to talk about this, but I have got to.

Secretary WILKIE. Well, I want to talk about it.

Senator TESTER. Well, I mean, here is the deal. It seems like every position I have ever been in in government, an elected position, over the last 20 years, has dealt with a fiasco when it comes to programming. We have spent about $2.5 billion so far, and I think—and correct me if I am wrong, Secretary Wilkie—there is a request for about $2.6 billion for electronic health records. I think everybody around the table, everybody on this Committee understands that this is important or we would not be allocating the money and we would not be pushing to get it done.

I guess the question is, and I know you have been impacted by COVID, but what have we gotten done so far? Have we got value for the money we have spent? What kind of timeline are we on here to get this up? Is it going to be user friendly enough, where we do

not have to send doctors and nurses to training for, you know, a month, to be able to get them to be able to understand how to use the damn record when they should be treating patients?

Secretary WILKIE. So this is a good-news story. I mentioned in my opening Statement that I believe VA has demonstrated that it is the most agile of the Federal departments. We have been working EHRM even this pandemic, and on April 18th we were able to show that the Joint Health Information Exchange works. We talk to DoD. DoD talks to us. The private sector can work the records.

We are going to be going live on the scheduling portion in Columbus, Ohio, and then I expect that Spokane and then later Seattle will be up and running sometime later this year.

You are correct that we took practitioners off of the program to put them on the front lines, but we are in a position that I do not think a lot of people thought we would be in. As a matter of fact, all 73 interfaces between DoD, VA, and the private sector now work, and I am confident that we have a good-news story here. It will revolutionize now. The increase that you are talking about is to spread—and it is something that is near and dear to your heart—the infrastructure remodeling of our institutions so that they can handle the electronics required for this system. As you know, particularly out West, many of our facilities have buildings that date back to the 19th century. That was certainly the case in Washington State, where we were testing this.

We are in a much better position than we were when I spoke to this Committee last.

Chairman MORAN. Senator Tester, Senator Sinema is available, and for us to make certain she has a chance to ask her question before we need to conclude for the vote, I am going to recognize her now.

SENATOR KYRSTEN SINEMA

Senator SINEMA. Thank you so much, Mr. Chairman, and thanks to the Committee for their patience with our technical issues. So thank you both for holding this hearing, Chairman Moran and Ranking Member Tester, and thanks to all our witnesses for being here today.

You know, organizations in Arizona supporting the homeless veteran community have continued to express concerns for the safety of those they serve and the staff that they employ. They also do not feel the VA is providing the necessary assistance to this vulnerable population during the coronavirus pandemic. One key reason is VA does not have a national coordinated plan to support homeless veterans. A national plan should include testing strategies for homeless populations, access to PPE for all staff working with these communities and plans to care for veterans who test positive for the coronavirus.

I know the VA is in need of additional flexibilities to fully support the homeless veteran community during this time, and I am proud to work with Senator Sullivan to introduce our Homeless Veteran Coronavirus Response Act of 2020, which will largely address the VA's needs.

But Secretary Wilkie, as we work to increase the resources and flexibilities, the VA has to support homeless veterans, it is impor-

tant for VA to lead on a national strategy, support the homeless veteran community, in collaboration with the organizations who provide direct services to the community.

What do you need to do this, and why has it not been done thus far?

Secretary WILKIE. Well, Senator, thank you, and I know that this Committee and you and Senator Sullivan have been working on this, and that is—your efforts are designed to give us more flexibility. I can tell you what we have been doing during this epidemic. We have used $300 million in additional funding to augment the three major programs that we have. First is the support to—supportive services for veterans and families, to increase the number of vouchers available for transition and housing. We have tripled the per diem amounts so that we are now addressing the basic food needs of our veterans, and we have augmented our emergency shelter programs.

In hot spots like Los Angeles, we have been out actively working with the community to bring veterans inside the fence. Regardless of whether they want to partake of our health care, getting them inside the fence at least allows them access to the food and to whatever services they will agree to have. But that is to protect them.

I will be announcing later this month our national roadmap on suicide prevention. As I said when I first addressed this with you, if it was just a roadmap looking at the last tragic act in a veteran's life it would not be worth much. So we are taking a broad look at not only mental health and addiction but also homelessness, the three things that, more often than not, those three areas that the Nation as a whole has ignored.

I will let Dr. Stone answer any of the medical questions that you have raised.

Dr. STONE. Senator, I appreciate your advocacy for this, and it is one of the areas that we are deeply concern. I talked earlier, as did the Secretary, about the financial instability and the risks to this population.

We have added $300 million through the supplemental funding to our support for homelessness. As you know that is a $1.83 billion program that we have asked to increase to $1.9 billion in 2021. Part of that is we have increased, by 70 percent, in the supportive services for veteran families, about $202 million that we have added to the $300 million that was already there. We have also added $88 million in the grant per diem. That is for emergency housing, primarily in hotels, to get veterans off the street, especially so that we can help manage the potential illnesses in that population.

As you know, in certain high-cost areas we were very gratified that HUD was given enhanced dollars to raise the amount for the HUD VASH vouchers. We have also added $10 million more to ensure that there is adequate personnel to work those.

But we continue to be pleased with your advocacy for this population as we work our way through this.

Senator SINEMA. Just a quick followup, because I know that my time is expiring, Mr. Chairman, and that is I would love to circle back and talk more about this. As we know, most of the efforts pro-

viding direct services to homeless veterans happens at the local level, outside of the VA system. I think that is what is leading this to be a somewhat disjointed operation throughout the country, and again why I am advocating so strongly for us to have a national strategy where we can work with our local partners outside of the VA facilities to address this pandemic.

Thank you, Mr. Chairman.

Secretary WILKIE. Um——

Senator SINEMA. I appreciate your time.

Chairman MORAN. Thank you, Senator Sinema.

Secretary WILKIE. Senator, let me indulge the Chairman's patience. I think that is one of the reasons why the Chairman has introduced the legislation that is still working its way through something that we support, that we have those more robust relationships with the States and localities, and charities, nongovernmental organizations, so that we can get into those places that VA is not.

I cannot thank the Committee enough for taking that idea that you have just expressed and putting it into action. I think this Committee has taken a huge step forward.

Senator SINEMA. Thank you. Thank you, Mr. Chairman.

Chairman MORAN. Thank you, Senator Sinema. I am going to ask just two quick questions, Mr. Secretary, and then I am going to see if Senator Tester has any quick questions, and we do then need to conclude our hearing. Two more questions related to community care, Mr. Secretary.

Your staff shared with my staff that there were 173,721 authorizations, excluding emergency and urgent care, were written for community care from March 24 to April 29, 2020, so while we have been through the pandemic. Could you tell me how many authorizations of community care were provided in that same timeframe a year ago, so I can make a comparison?

Secretary WILKIE. I am going to have to take that for the record, and I believe we are getting that information to your staff.

Chairman MORAN. Thank you.

Secretary WILKIE. Yes, sir.

Chairman MORAN. Second, your reopening plan mentions that the VA will schedule community care and virtual care appointments where, quote, "clinically appropriate." I want to make certain that the veteran is front and center and that "clinically appropriate" is not a phrase that will be used to deny community care as appropriate, which, in most instances, is when it is in the best interest of the veteran.

Secretary WILKIE. Yes, sir. Your interpretation is my interpretation. I would also add that what I have seen during this epidemic with veterans is similar to what practitioners have seen across the country. Most instances of veterans not going into the community have been on their wishes, and we are going to do everything we can to ramp this thing up back to where it was. Sixty percent is not good enough. It is not in line with the forums that you have championed and the forums that I believe in.

Chairman MORAN. So "clinically appropriate" is not an impediment to MISSION and CARE Act in the community?

Secretary WILKIE. No, sir.

Chairman MORAN. Thank you. Senator Tester?

Senator TESTER. Thank you, Mr. Chairman. Very quickly, the Chairman mentioned this in his opening remarks, and it has been alluded to throughout this hearing. Because especially with COVID–19 I think that the challenges around mental health are going to increase. I appreciate the work that you and your staff have done with our staffs to make sure that the John Scott Hannon bill is ready for prime time. I would encourage you to keep that up, and I will encourage my side to keep that up, because I think this bill is important. I do not think that Senator Moran and myself would have introduced it if we did not think that veteran mental health is a problem, and I do not think you guys see it any differently either. We have just got to get this going, because I am not sure that we have got our arms around it yet. So we need to use every tool we have available.

If you would like to comment to that, you can, but I would just like to say I appreciate working on it, and I think we need to get it done. It did pass the Committee unanimously, and you know the differences of the political spectrum on this Committee are wide. We all agreed that this was the right thing to do.

The last thing I would say, in closing, and thank you, Mr. Chairman, is that, you know, you guys, I have been looking at you on TV for the last 2 hours, and I would just tell you that if you decide to give up the VA, all four of you could be news announcers on your local TV stations.

Secretary WILKIE. Thank you, sir.

Chairman MORAN. Senator Tester, I do not know whether there was a compliment in there. I was distracted. But I agree——

Senator TESTER. They look good.

Chairman MORAN. But I will assume there was a compliment there.

Secretary WILKIE. I agree with your Statement.

Senator TESTER. They look really good. Even on high def they look good.

Secretary WILKIE. I agree with your sentiment about the legislation. It is vital.

Chairman MORAN. Senator Tester, there are two bills pending unanimous consent request in the Senate. I was informed today that I think one of them is ready. The other, it is cleared on our side and not yours. If you would check with your staff. This is something that you and I both support and something that the Department has been asking for.

Senator TESTER. I am on it, Jerry. Thank you.

Chairman MORAN. Thanks very much, Jon.

Mr. Secretary, I always give witnesses in front of my committees the opportunity to clarify, to retract, make any corrections of something that they said or something that wish they had said.

Secretary WILKIE. I will go back and look, but that is not going to stop me from thanking the Committee, as I did at the beginning. There is no better committee when it comes to the oversight of the Department for which you have responsibility, or a more collaborative committee.

I do want to say one thing. Thousands of VA employees have put themselves in harm's way. I think they—well, I do not think—they

deserve the thanks of the American people. We have opened our hospitals. We have sent people into extremely dangerous situations. They have responded magnificently. One of the things I would add is that we actually have a lower absentee rate and a lower leave request rate this year than we did last year, because people have responded to the call to duty, as they always do, and I am very proud to be part of their family. I thank you, sir.

Chairman MORAN. Mr. Secretary, thank you for your presence and your team here today. I thought the hearing was valuable and I appreciate your testimony and our conversations. I would express my gratitude on behalf of all Kansans, on behalf of all Americans for the men and women who work at the Department of Veterans Affairs, many of them veterans themselves, who arose to the cause of caring for their brothers and sisters at the Department of Veterans Affairs. We are very grateful for the risks they take and the anxiety they and their families must have about that service. So thank you for your reiteration of that, and I join you in that sentiment.

Secretary WILKIE. Thank you, sir.

Chairman MORAN. The Disabled American Veterans, the Paralyzed Veterans of America, and the Veterans of Foreign Wars have each year produced an independent budget based on their analysis of the funding needs of the VA. For this hearing we asked those VSO partners to submit written testimony on the President's budget request for the VA, and they provided valuable feedback. They have done so, and without objection I will include their written testimony into the record. So ordered.

Chairman MORAN. Committee members, you have the opportunity to submit for us today additional questions for the witnesses. Please do so in the next 5 days. Mr. Secretary, please ask your Department to respond as quickly as possible to our Committee's further question.

Secretary WILKIE. Yes, sir.

Chairman MORAN. Without further conversation we are adjourned.

[Whereupon, at 5:02 p.m., the Committee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

U.S. SENATE COMMITTEE ON
VETERANS' AFFAIRS
CHAIRMAN JERRY MORAN

Senate Veterans' Affairs Committee Hearing:
Review of the FY2021 Budget and FY2022 Advance Appropriations Request and Oversight of CARES Act Supplemental Appropriations for the Department of Veterans Affairs

Opening Statement Chairman Jerry Moran (R-Kan.)
Wednesday, June 3, 2020 | 3:00 p.m.

As Prepared for Delivery:

Good morning, everyone. The committee will come to order. Today's hearing is on the VA's fiscal year 2021 budget request and the supplemental appropriations contained in the CARES Act to respond to the COVID-19 outbreak.

We welcome Secretary Robert Wilkie as well as Dr. Richard Stone, executive in charge of the Veterans' Health Administration, Dr. Paul Lawrence, Under Secretary for Benefits, and Jon Rychalski, Assistant Secretary for Management and Chief Financial Officer. I appreciate your presence today and look forward to discussing how we can work together to improve outcomes for veterans in our country.

Before we proceed to the topic of today's hearing, I would like to take a moment to recognize that last Monday was Memorial Day. As we should every day, we take time as a nation to pause and remember the brave Americans who gave their lives in defense of our country, and we honor the sacrifice they made to keep us free.

In that spirit, I want to acknowledge the passing of veterans and VA personnel who lost their lives due to COVID-19. Part of our discussion today is to make certain the VA has everything it needs to minimize the loss of life during these unprecedented times. I also want to thank VA nurses, doctors, and support staff who are working tirelessly to deliver care to veterans during the COVID-19 pandemic. In addition to serving veterans, the VA has executed its "fourth mission" to support the American health care systems struggling during this national emergency. The response from these health care professionals has been and continues to be admirable.

While the VA continues to devote resources to suppress the pandemic, veterans will continue to rely on VA for their needs, such as education, home financing, and transition services. To this end, the pursuit of the wellbeing of our nation's veterans must continue unabated.

Between the release of this budget and today's hearing, Congress passed legislation to support federal agencies responding to the COVID-19 emergency.

Following a supplemental appropriations request from the president, Congress passed the CARES Act, signed into law on March 27th.

CARES provides $19.6 billion for medical services, including telehealth services, equipment and supplies, personal protective equipment, and emergency room and urgent care. CARES also sets aside $2.2 billion for IT in order to increase telework capacity and other telehealth needs.

I am interested to learn how the COVID-19 emergency has affected VA health services and its budget. Retrospectively, did the CARES Act appropriate funds in the right places, and prospectively, given the shifting health care demands, does the president's fiscal year 2021 budget still address VHA's projected needs?

Released before the COVID-19 emergency, the president's fiscal year 2021 budget request includes a proposed increase of $22.8 billion in funding for the VA for a total of $243.4 billion. This represents a 10.2 percent increase above fiscal year 2020 enacted levels. I look forward to hearing from you how the proposed budgetary increase will create better outcomes for veterans.

I was pleased to see the budget request includes an increase for Medical Community Care as the VA continues to implement the MISSION Act. As we have discussed, many veterans, especially those in rural states like Kansas, depend on community care providers for access to timely, quality care. MISSION Act was a bipartisan effort to transform veterans' access to community care, it is strongly supported by every Veteran Service Organization and you have been a champion to ensure its proper implementation, Mr. Secretary. We all want veterans to receive the care they need through the VA or in their community, and I look forward to discussing the future of MISSION Act today.

Addressing another of the committee's health priorities, I appreciate the additional requested funding for mental health and suicide prevention services. I know you share this priority Mr. Secretary. In January, this committee unanimously reported the Commander John Scott Hannon Veterans Mental Health Care Improvement Act to provide targeted resources towards research, grants for community partners, and improved coordination between the Department of Defense and the VA to quell the rates of veterans who die by suicide.

It is my hope that you will continue working with us to get this bill signed into law.

Mr. Secretary, again, I thank you for being here. I appreciate the difficulty of your job as the administration works to find a whole-government solution to the pandemic. I look forward to hearing your views on the FY21 budget, and I now turn to my colleague and friend, the senator from Montana, Senator Tester, for opening remarks.

STATEMENT OF
THE HONORABLE ROBERT L. WILKIE
SECRETARY OF VETERANS AFFAIRS
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
SENATE COMMITTEE ON VETERANS' AFFAIRS
BUDGET REQUEST FOR FISCAL YEAR 2021

JUNE 3, 2020

Good afternoon, Chairman Moran, Senator Tester, and distinguished Members of the Committee. Thank you for the opportunity to testify today in support of the President's Fiscal Year (FY) 2021 Budget for the Department of Veterans Affairs (VA), including the FY 2022 Advance Appropriation (AA) request. I am accompanied today by Dr. Richard Stone, Executive in Charge, Veterans Health Administration (VHA); Dr. Paul Lawrence, Under Secretary for Benefits, Veterans Benefits Administration (VBA); and Jon Rychalski, Assistant Secretary for Office of Management and Chief Financial Officer.

I begin by thanking Congress and this Subcommittee for your continued strong support and shared commitment to our Nation's Veterans, especially during this extraordinary response to the Coronavirus pandemic. From the start VA took an aggressive posture to protect our patients from COVID-19, and our staff has worked tirelessly to continue and carry it out, with great success. We have diagnosed more than 12,000 Veterans with a positive test for the Coronavirus, but more than 9,400 percent of them are 14 days past a positive test. We're treating about 1,400 patients for the virus today. I am proud to report that we are adequately stocked with supplies, including at least two weeks' worth of N95 masks and other Personal Protective Equipment (PPE) for our health care staff. We do not have any major staffing problems to report and, in fact, our attendance has been better this year than over the same period last year, a sign of a very dedicated workforce. Overall, our infection rate among VA staff is incredibly low, less than one half of one percent. To add support, we have greatly expedited the hiring process and brought on more than 10,000 health care staff in an effort to stay ahead of the problem.

I want to thank the Congress for the $19.6 billion in supplemental funding provided in the Coronavirus Aid, Relief, and Economic Security (CARES Act) to address this crisis. This funding has provided us with the means to protect Veterans, including those most vulnerable, our employees, and our citizens during this historic crisis. This includes $17.2 billion for VHA, where money is being used to hire new staff and make sure existing personnel have the resources they need to deal with the evolving needs of the pandemic. The funding has also been used to add beds, provide overtime pay and purchase needed supplies such as ventilators, pharmaceuticals, and personal protective equipment

Returning to the subject of today's hearing, with the funding provided by Congress, VHA provides high quality health care services to 9.3 million enrolled Veterans; VBA provides educational benefits for over 900,000 beneficiaries and guaranteed over 624,000 home loans; and our National Cemetery Administration (NCA) will inter an estimated 137,600 Veterans and care for over 4 million gravesites in our 156 sacred National Cemeteries. We are on the other end of the national security continuum, as we take care of those who have already borne the battle, and I continue to believe this is one of the noblest missions in government.

Progress

Solid progress on some of the most transformational initiatives in VA's history has taken place in the last 18 months, with the result being a string of wins that puts Veterans front and center where they belong.

One of our most notable accomplishments is the near-flawless implementation of the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 signed into law by President Trump in 2018, giving Veterans real choice over their health care decisions. Emboldened by predictions of an imminent VA system collapse, we effectively rolled out this landmark legislation with no disruption to Veteran care. Less than 5 months after the rollout of the VA MISSION Act's community care provisions, VA had made more than 2.2 million referrals to community care. In addition, we implemented a new urgent care benefit and more than 90,000 urgent care visits had been completed in the same timeframe, and it is only becoming more popular with Veterans. In October 2019, eligible Veterans sought more than 5,000 urgent care visits each week, thanks to the 6,400 local urgent care providers that have contracted to provide this benefit for VA. During the COVID-19 pandemic, with large segments of the private sector health care system at limited capacity or closed, VA has been able to ensure approximately sixty percent of our referrals to community network providers were fulfilled.

Success with the VA MISSION Act had tremendously positive second and third order effects. Because Veterans like what they see, VA is delivering more care overall than ever before. In FY 2019, VA completed more than 59.9 million internal episodes of care – a record high and about 1.7 million more than the year before. Even better, Veterans' overall trust in VA now sits at 80 percent, as compared to 55 percent in 2016. Statistics show:

- Eighty-nine percent of Veterans now trust the VA health care they receive;
- In a recent Veterans of Foreign Wars survey, nearly three quarters of respondents reported improvements at their local VA; and
- More than 90 percent said they would recommend VA care to other Veterans.

We expanded other venues of care for Veterans as well. VA is a leader in using telehealth technology to diagnose and treat Veterans remotely, by connecting Veterans with health care providers electronically, sometimes in their own homes. In FY 2019,

VA exceeded 2.6 million telehealth episodes of care to more than 900,000 Veterans. To increase access to telehealth services, VA has established multiple innovative agreements for 'Anywhere to Anywhere' connected care programs with Walmart, Philips, T-Mobile, Sprint, TracPhone SafeLink, and Verizon. These partnerships give Veterans who may need help with Internet service more options to connect with VA health care providers through video telehealth.

We have also tackled some of our most pressing social issues: opioid use disorder (OUD), homelessness, and a regrettable scourge on our society: suicide.

President Trump's 2018 Initiative to Stop Opioids Abuse and Reduce Drug Supply and Demand directly contributed to a 19 percent reduction in the number of patients receiving opioids nationwide. Overall, since the President took office, there has been a 35 percent decline in Veterans being dispensed an opioid from a VA pharmacy.

VA has achieved impressive results in fighting Veteran homelessness by working with local governments, companies, and other stakeholders. In FY 2018, the total number of Veterans experiencing homelessness decreased 5.4 percent, and in 2019, that number dropped another 2.1 percent. As of February 2020, VA has served over 200,000 Veterans and their families by housing them or preventing them from becoming homeless. Thanks to these partnerships, we've seen 78 communities and 3 states effectively end Veteran homelessness.

The success of these partnerships suggests it's a good way to reduce Veteran suicide, and so VA adopted a public-health approach to suicide prevention, which focuses on equipping communities to help Veterans connect with local support and resources. The public-health approach is central to VA's first ever National Strategy for Preventing Veteran Suicide, which was published in 2018, as well as the President's Roadmap to Empower Veterans and End a National Tragedy of Suicide (PREVENTS) Executive Order (EO) 13861. PREVENTS aims to bring together stakeholders across all levels of government and the private sector to address the national suicide epidemic and provide our Veterans with the specific mental health and suicide prevention services they deserve.

Our recent successes reveal the magnitude of change occurring at VA. But it is only part of the story because we have even more fundamental changes to how VA operates on the cusp of deployment. VA is on the verge of delivering the Centralized Scheduling Solution (CSS) at Chalmers P. Wylie VA Ambulatory Care Center in Columbus, Ohio and VA's new electronic health record (EHR) solution at Mann-Grandstaff VA Medical Center (VAMC) in Spokane, WA, followed by VA Puget Sound Health Care System (HCS) in Seattle and American Lake, WA. Congress has made it clear, and I have always maintained, that we not rush to implement a new EHR at the sacrifice of the quality patient care we promised and are committed to delivering to our Veterans and other beneficiaries. To prioritize the health and safety of our Veterans and front-line staff, the Office of Electronic Health Record Modernization (OEHRM) is responding to changing conditions at VA facilities and changing priorities for the

Department. OEHRM is working to be as non-intrusive as possible to ensure that facility staff are equipped to respond to increased patient demand and staffing requests. In light of these rapidly evolving events tied to the spread of the pandemic, programmatic and budgetary impacts are being assessed.

After implementation at our initial sites, the new EHR will be delivered to over 1,200 VA hospitals and clinics through a phased deployment strategy. Concurrent with the deployment of our new EHR modernization is the installation of a new medical logistics system, the Department of Defense's (DoD) Defense Medical Logistics Standard Support (DMLSS) system. We are also deploying our new accounting and acquisition system, the integrated Financial and Acquisition Management System, to NCA with full implementation across VA following in the coming months and years.

The magnitude of change has been so great, and the pace so quick, that VA must carefully assess our resource needs to ensure we can adequately sustain what we have accomplished while continuing to make investments in key areas that promise the greatest return for our dollars. It is against that backdrop that our FY 2021 Budget was developed, with emphasis on sustaining the ground we have gained.

Fiscal Year 2021 Budget Request

The President's FY 2021 Budget requests $243.3 billion for VA — $109.5 billion in discretionary funding (including medical care collections). The discretionary request is an increase of $12.9 billion, or 14.1 percent, over the enacted FY 2020 appropriation. It would sustain the progress we have made; provide additional resources to improve patient access and timeliness of medical care services for the approximately 9 million Veterans enrolled in VA health care; and improve benefits delivery for our Veterans and their beneficiaries. The President's FY 2021 Budget also requests $133.8 billion in mandatory funding, $9.1 billion or 7.2 percent above 2020.

For the FY 2022 AA, the budget requests $98.9 billion in discretionary funding including medical care collections for Medical Care and $145.3 billion in mandatory advance appropriations for VBA's benefits programs: Compensation and Pensions; Readjustment Benefits; and Veterans Insurance and Indemnities.

For Medical Care, VA is requesting $94.5 billion (including $4.5 billion in medical care collections) in FY 2021, a 13 percent increase over the 2020 level (including the $615 million transfer from the Veterans Choice Fund), and a $2.3 billion increase over the 2021 AA. This excludes CARES Act funding. The request fully supports sustainment of the provisions included in VA MISSION Act, including the streamlining and enhancement of community care services, an urgent care benefit, expansion of our caregiver support program, and other authorities and programs that will improve VA's ability to provide high-quality, timely, Veteran-centric care in line with Veterans' preferences and clinical needs.

This is the largest budget request in VA history, allowing VA to sustain our remarkable progress, continue the upward trajectory of modernizing our systems, and be a center of innovation, providing options to Veterans when it comes to their own care. I urge Congress to support and fully fund our FY 2021 and FY 2022 AA budget requests.

Next, I will highlight progress we have made, as well as planned activities, in health care, benefits, business transformation, infrastructure, and cemetery operations among others and how the resources we are requesting will contribute to our continued success.

Health Care

VA Medical Centers

In January 2019, VHA began an initiative to optimize clinic practice management and improve access to care through the Improving Capacity, Efficiency, and Productivity initiative. The goal of the initiative was to leverage existing resources and increase internal capacity to maximize the care we provide inside VA with the enhanced eligibility for community care under the VA MISSION Act. The project consisted of a 3-phased approach: Phase 1 focused on improving data accuracy (of labor mapping, bookable time, Primary Care Management Model, stop codes, and person class) through a combination of organization-wide webinars and one-on-one support via virtual site visits; Phase 2 centered on implementation of tailored strong practice solutions (based on process measure data) to help medical centers maximize capacity using existing resources; and Phase 3 encouraged VAMCs to leverage innovative methods of care, such as clinical resource hubs, clinical contact centers, e-consults, and telehealth services.

Through this effort, the number of VAMCs that met the VA MISSION Act average wait time standard of less than or equal to 20 days jumped from 47 percent to 65 percent. To replicate this success, we adopted these same practices at an additional 30 VAMCs. As of February 2020, the initiative entered the monitor and sustainment phase as VHA continues to ensure access enhancements.

Over the last several years, we have also increased provider staffing levels significantly. In FY 2019, prior to the hiring surge in response to the Coronavirus pandemic, we increased physician staffing levels by 1.5 percent; Nurse Practitioners by 4.9 percent; and Physician Assistants by 3.9 percent. We also increased clinic support staff for providers and delivered an additional 2.8 million total clinical episodes of care in FY 2019. In FY 2019, physician workload increased by 2 percent with over 72 million physician encounters. Clinical workload of physicians, measured in a common relative value unit scale that considers the time and intensity of the service, increased by 4 percent. Provider productivity remained relatively constant.

Community Care Network

We continue our successful deployment of the Community Care Network contracts, which use third party administrators (Optum Public Sector Solutions in Regions 1, 2, and 3; TriWest Healthcare Alliance in Region 4; contracts for Regions 5 and 6 are still in progress) to provide a credentialed network of providers for community care. Regions 1 and 2 are fully deployed; Region 3 is in progress; and Region 4 deployment will begin later this month. Our robust network of over 880,000 providers across the United States gives us exceptional flexibility in meeting Veterans' health care needs no matter where they reside. Realizing that we needed to do a better job of paying claims from community providers, our contracts require administrators to process and pay claims from the community providers based on the more stringent timelines included in the VA MISSION Act. The FY 2021 Budget requests $18.5 billion for Community Care, an increase of 21 percent over the FY 2020 funding level. These resources will allow us to provide real choice to our Veterans, and we estimate we will have 33 million visits to community care providers in FY 2021, an increase of 3.9 percent over FY 2020.

Caregiver Support Program

As we implement the VA MISSION Act, we are expanding our caregiver program to family caregivers of eligible Veterans from all eras. Under the law, expansion will begin when VA certifies to Congress that VA has fully implemented a required information technology (IT) system. The expansion will occur in two phases beginning with eligible family caregivers of eligible Veterans who incurred or aggravated a serious injury in the line of duty on or before May 7, 1975, with further expansion beginning two years after that. The 2021 Budget request for the Caregivers Support Program (CSP) is $1.2 billion, $650 million of which is specifically to implement the program's expansion. In October 2019, VA successfully launched a replacement IT solution, known as the Caregiver Record Management Application (CARMA), to support the program. Our efforts in FY 2020 are focused on automating stipend payments and improving existing functionality. Over the course of the next year, we will implement interprofessional Centralized Eligibility and Appeals Teams. This is intended to improve consistency in Program of Comprehensive Assistance for Family Caregivers (PCAFC) eligibility determinations across the enterprise. Led by physicians, these teams will assist with evaluating PCAFC eligibility, tier changes, revocations, and appeals. To ensure smooth operations following PCAFC expansion, VA is working aggressively to recruit, hire and train new team members. These interprofessional teams will be phased in over the course of the next several months and VA anticipates them being fully mission capable in fall 2020.

Some additional key initiatives include the hiring of a program Lead Coordinator at every Veterans Integrated Service Network (VISN) to standardize care and services. We also implemented the Annie Text system to alleviate caregiver stress and burden through supportive text and developed a toolkit for caregivers that educates and provides resources for caregivers on how to recognize and respond to suicide warning signs. CSP continues to develop, implement, and refine services including peer

support, caregiver self-care, and dementia care as well as modernizing processes, programming, and staffing to better serve our Nation's Veterans and their caregivers. As of February 2020, over 350 new staff have been added to the program with the goal of hiring approximately 680 more staff in FY 2020. To continue to support the expansion for this program under the VA MISSION Act, ongoing workload modeling will be assessed, and additional staff may be required.

Suicide Prevention and Treatment

On March 5, 2019, President Trump signed the *National Roadmap to Empower Veterans and End Suicide* (EO 13861), also known as PREVENTS. This created a Veteran Wellness, Empowerment, and Suicide Prevention Task Force that is tasked with developing, within 1 year, a road map to empower Veterans to pursue an improved quality of life, prevent suicide, prioritize related research activities, and strengthen collaboration across the public and private sectors. This is an all-hands-on-deck approach to empower Veteran well-being with the goal of ending Veteran suicide. The road map is on track to be delivered to the White House in the coming weeks. The PREVENTS Office will then work with government agencies on the Task Force, private-sector entities, and State and local communities to implement the recommendations. The FY 2019 Suicide Prevention and Treatment budget was fully executed as planned, supporting the Veterans Crisis Line as well as other critical clinical and community suicide prevention efforts. The FY 2021 Budget requests $10.2 billion for mental health services, a $683 million increase over FY 2020. The Budget specifically would invest $313 million for suicide prevention programming, a $76 million increase over the FY 2020 enacted level. The request would fund over 19.7 million mental health outpatient visits in a mental health setting, an increase of nearly 272,000 visits over the FY 2020 estimate. This builds on VA's current efforts. Since June 2017, VHA has hired 6,047 mental health providers, which is a net increase of 1,754 providers serving our Veterans. Suicide is a national public health issue that affects all Americans. Suicide prevention is my top clinical priority and we are actively implementing a comprehensive public health approach to reach all Veterans — including those who do not receive VA benefits or health services.

Opioid Safety & Reduction Efforts and Treatment of Opioid Use Disorder

The FY 2021 Budget includes $504 million, a $79.1 million increase over FY 2020, to address treatment of OUD and opioid safety and reduction efforts, including specific funding related to programs supported through the Comprehensive Addiction and Recovery Act (CARA) of 2016, Public Law 114-198. Funding for CARA programs is included in the FY 2021 Budget at the level of $121 million, a $64.6 million requested increase over advanced appropriation previously approved for FY 2021 to specifically address over-reliance on opioid analgesics for pain management, improve access to treatment for OUD, and to provide safe and effective use of opioid therapy when clinically indicated. This CARA budget would provide support for deployment of evidence-based practices, toolkits, and research to enhance and expand patient-centered, safe, and effective pain care. This will be accomplished through several

efforts including: developing and implementing a national program for Opioid Stewardship that will enhance the continued expansion and implementation of the Opioid Safety Initiative; providing funding for fully staffing and supporting CARA-required Pain Management Teams with hiring, toolkits, training and expert guidance; and providing increased access to interdisciplinary pain management through multiple modalities including but not limited to: increased field staffing for pain management teams at facilities; greatly expanded access to telehealth for pain management; and treatment of OUD so that we can reach all Veterans under our care. Another particularly important risk mitigation strategy for opioids, and for all controlled substance, is access to State Prescription Drug Monitoring Programs (PDMP), which allow for safer prescribing. VA is working towards an automated process of PDMP queries that can be accessed within EHR by prescribers and their delegates and therefore integrates into the clinical workflow. We expect this to be implemented in early FY 2021. VA is in the process of integrating PDMPs into both the legacy health records system and the new EHR. PDMP's solution for the legacy system will provide integrated access for clinicians and delegates across the available state data bases and the Military Health System. VA's new EHR will initially provide integrated access to prescribers directly to the Washington state PDMP.

Multiple initiatives are underway to increase access to life-saving medication for OUD. In the past 4 years, the number of Veterans with OUD receiving buprenorphine, injectable naltrexone, or opioid treatment program administered methadone increased by more than 20 percent. Most of these medications are provided in substance use disorder treatment clinics, but only about half of Veterans clinically diagnosed with OUD receive treatment in these clinics. In order to reach Veterans where they are, VA launched the Stepped Care for Opioid Use Disorder Train-the-Trainer initiative to increase access to OUD medication treatment in Primary Care, General Mental Health, and Pain Management Clinics. In the first 14 months, 18 pilot teams increased the number of patients receiving buprenorphine in these clinics by 141 percent. During FY 2020 and continuing into FY 2021, VA plans to provide additional training and support to access stepped care for OUD treatment in settings outside of substance use disorder specialty care with future plans focused on ensuring timely access to life saving medication for the treatment of OUD regardless of where the Veteran presents for care.

VA's Opioid Safety Initiative has greatly reduced reliance on opioid medication for pain management, in part by reducing opioid prescriptions by more than 58 percent since 2012. Seventy-five percent of VA's reduction can be attributed to not starting Veterans with chronic, non-cancer pain on long-term opioid therapy and instead utilizing multimodal strategies that manage Veteran pain more effectively long-term. As VA continues its efforts to address opioid over-use in a Whole Health (WH) approach to care, options such as non-opioid medications and non-pharmacological modalities including: behavioral therapy; restorative therapies (such as physical therapy and occupational therapy); interventional pain care; complementary and integrative health (CIH) approaches (such as massage therapy, yoga, meditation, acupuncture, Tai Chi) are important components to VA's Pain Management Strategy. Initial results from the analysis of the 18 White House Flagship sites as required by CARA have just become

available and demonstrate a three-fold reduction in opioid use among Veterans with chronic pain who used WH services (including CIH) compared to those who did not. Monitoring will continue of these original 18 sites as well as the 37 additional facilities that were added in 2018. As required by CARA, all VHA facilities have established or are in the process of implementing interdisciplinary pain management teams or pain clinics that support Veterans and our Primary Care Teams in delivering the best pain care possible. While these efforts are well underway, we must continue to provide access to these safe and effective pain care approaches systemwide, wherever the Veteran is located and virtually, as needed. In addition, the Creating Options for Expedited Recovery (COVER) Commission, after reviewing the status of mental health care in the VA, recommended that VA should continue to expand the availability of the Whole Health approach in the treatment of OUD as well as mental health issues overall.

Women Veterans

The number of women Veterans enrolling in VA health care is increasing, placing new demands on VA's health care system. Women make up 16.9 percent of today's Active Duty military forces and 19 percent of National Guard and Reserves. More women are choosing VA for their health care than ever before, with women accounting for over 30 percent of the increase in Veterans served over the past 5 years. The number of women Veterans using VHA services has tripled since 2001, growing from 159,810 to over 500,000 today. To address the growing number of women Veterans who are eligible for health care, VA is strategically enhancing services and access for women Veterans by investing $50 million in a hiring initiative in 2021. The FY 2021 Budget projects $626 million for gender-specific women Veterans' health care, a $53 million increase over FY 2020. This Budget would also continue to support a full-time Women Veterans Program Manager at every VA health care system. VHA has also made a commitment to train mental health providers to address women Veterans' complex and unique needs, including gender-related suicide risks. One of our key initiatives is the Women's Mental Health Mini-Residency and national Reproductive Mental Health/Psychiatry consultation initiatives. To date, more than 450 VA providers have attended the mini-residency. Participants indicate that the training increased their competency to provide gender-sensitive care to women Veterans and positively impacted women's mental health services at their local facility. The mini-residency is required training for all Women's Mental Health Champions, who serve as a local contact for women Veterans' mental health.

Additionally, VA launched a National Women's Reproductive Mental Health Consultation Program in FY 2020. With this new resource, expert consultation is now available to all VA clinicians on topics such as treating premenstrual, perinatal, and perimenopausal mood disorders, and treating women's mental health conditions that can be affected by gynecologic conditions. Without this program, key mental health care needs of women might not be detected or treated. User feedback has been overwhelmingly positive. Consultations have focused on highly complex patient presentations and prescribing considerations and reaffirm the critical need for this national resource.

This Budget would continue to support Women's Mental Health training and consultation programs. It would also support 0.10 Full-Time Equivalent (FTE) protected time for a Women's Mental Health Champion at every VHA health care system to facilitate consultations and develop resources that increase the visibility and accessibility of gender-sensitive women's mental health care and contribute to a welcoming care environment.

Treatment of Military Sexual Trauma

When asked by their VA health care provider, about 1 in 3 women and 1 in 100 men report that they experienced sexual assault or sexual harassment during their military service. These experiences, which VA refers to as military sexual trauma (MST), can have a significant impact on Veterans' mental health, physical health, general well-being, and are also associated with an increased risk for suicide. VA's services for MST can be critical resources to help Veterans in their recovery journey. Since VHA began systematic MST-related monitoring in FY 2007, there has been a 344 percent increase in the number of female Veterans receiving MST-related outpatient care and a 256 percent increase in the number of male Veterans receiving MST-related outpatient care. In FY 2019, VA provided 2,014,671 MST-related outpatient visits— an 11 percent increase from FY 2018. The cost of providing MST-related care is incorporated into broader health care costs for each VA health care system (HCS) and, as such, VHA's requested increases for health care services funding more broadly will directly benefit MST survivors. These funds are needed to maintain the full continuum of outpatient, inpatient, and residential mental health services as well as medical care services that are crucial to assisting MST survivors in their recovery. Funding also supports VHA's universal screening program in which every Veteran seen for health care is asked about experiences of MST, so that he or she can be connected with MST-related services as appropriate. Additionally, funding supports the MST Coordinator program, in which every VA health care system has a designated MST Coordinator who can help Veterans access MST-related services and programs.

Precision Oncology

The FY 2021 Budget includes $75 million to support VHA's precision oncology initiative, which aims to improve the lives of Veterans with cancer by ensuring that no matter where they live, they have access to cutting-edge cancer therapy using Precision Medicine, telehealth, and a learning HCS that integrates research with clinical care. Precision oncology is an evolution from one-size-fits-all cancer care. We are learning that we can increase treatment success and decrease side-effects by picking the treatment based upon characteristics of the patient and of the cancer. It primarily focuses on mutations in the patient's and cancer's DNA, respectively. The requested FY 2021 funding for this initiative would support:

- Investment in new national lung cancer network, including expansion of lung cancer screening, and expanded prostate cancer coverage;

- Enhanced ability to track – and conduct performance improvement – across a broader range of precision oncology quality measures at the national level;
- Scaling access to genetic counseling with the growth of genetic testing;
- Expanding access to national tele-oncology;
- Expanding use of pharmacogenics to enhance safety and efficacy of medication use;
- Additional clinical trials for prostate and lung cancer; and
- Exploration of new opportunities for breast cancer research.

Telehealth

The FY 2021 Budget request includes $1.3 billion for care provided through telehealth. VA leverages telehealth technologies to enhance the accessibility, capacity, and quality of VA health care for Veterans, their families, and their caregivers anywhere in the country. VA achieved more than 1.3 million video telehealth visits in FY 2019, a 26 percent increase in video telehealth visits over the prior year. Representing the fastest growing segment of VA telehealth, more than 10 percent of the 900,000 Veterans using VA telehealth received care through video telehealth in the comfort of their home or another non-VA location using VA Video Connect (VVC). In response to the pandemic, the Office of Information and Technology rapidly scaled telehealth platforms to stay ahead of business and user demand. VA has seen a near tenfold increase in VVC visits, from nearly 10,500 the first week of March to 104,387 visits in the first week of May. Recently, VA recorded its first day with 2 million minutes of VVC visits. As of May 20, 35 percent of VVC traffic is being routed to VA's Care2 cloud, expanding bandwidth and improving call quality and performance. In FY 2021, our goal is to have all VA providers offering VA Video Connect services to Veterans when clinically appropriate and requested by the Veteran.

Strengthening VA's Internal System of Care

The FY 2021 Budget supports VHA's Plan for Modernization including continued progress towards becoming a high reliability organization (HRO) and the realignment of VHA Central Office (VHACO) to better support our care providers in the field. The HRO model is the managerial framework for transformational change. HROs focus on continuous improvement and enhancing the customer experience. VHA has identified its own path to high reliability to meet Veterans' unique needs. Starting in 2019, VHA began instilling HRO principles, tools, and techniques at every level of the organization to address root causes; advance VA and VHA priorities; and ultimately achieve our vision of providing exceptional, coordinated, and connected care for Veteran health and wellbeing. In FY 2021, VHA will continue to promote HRO principles and move closer to its aim of becoming a "zero harm" organization that is constantly learning and applying those lessons toward improving Veteran care. On January 8, 2020, VA announced the redesign of VHACO as part of its modernization efforts to reflect leading health care industry practices and address clinical integration. The new structure now supports joint leadership roles of a chief medical officer and expanded chief nursing officer. The new structure clarifies office roles and streamlines responsibilities to

eliminate fragmentation, overlap, and duplication. It also allows VHA to be more agile and to respond to changes and make decisions more quickly. This positions VHA to better support Veterans Integrated Service Networks (VISN) and facilities directly serving Veterans. VHACO staff includes the approximately 20,000 staff located throughout the country that provide operational support to VAMCs. The proposed change in structure will not result in a reduction or termination of staff.

Animal Research

VA conducts an array of research in areas significant to Veterans' health care. VA only conducts research with animals when absolutely necessary. There are some research questions that cannot be addressed other than by research with animals, and VA refuses to ignore Veterans whose health care needs that research. For example, animal research in Cleveland involving researchers from VA recently led to the development of a device that allows Veterans with spinal cord injuries to cough on their own and communicate with a stronger voice, leading to increased independence and a significant reduction in respiratory infections and deaths. This important advancement would not have been possible using computer simulations, test tube techniques, 'organ on a chip' technology, or smaller animal species. VA has very few animal studies active at any one time, but some health care problems like this one can only be addressed with animal research, underscoring the importance of this kind of research in helping Veterans who have been severely injured on the battlefield.

Benefits

Blue Water Navy

One of the most significant changes for our Veterans in 2019, was the signing of the *Blue Water Navy Vietnam Veterans Act of 2019* in June, with an effective date of January 1, 2020. As of April 30, 2020, VA has received nearly 56,000 potential Blue Water Navy (BWN) claims and has already issued over $425 million in retroactive benefit payments to more than 20,000 BWN Veterans and survivors. All IT systems were operational on December 31, 2019 and continue to address the necessary requirements. In FY 2021, VA expects to receive 70,000 BWN claims and appeals. VA's FY 2021 funding request includes $137 million for VBA General Operating Expenses (GOE) to support BWN implementation. This Budget request includes sustaining 691 FTE for claims processing; call center agents; quality reviews; and contracting for the continued scanning of deck logs, service records, and paper claims from the National Archives and Records Administration. The Budget also supports standard business operations, which include support to enable Private Medical Records requests, audit reviews of deck log transcription services, and strategic communications/outreach to Veterans and key stakeholders.

Forever GI Bill

The FY 2021 Budget for VBA includes an increase of $20.5 million as a result of provisions in The Harry W. Colmery Veterans Educational Assistance Act (the Colmery Act) of 2017. The Department remains steadfast in its commitment to ensuring every Post-9/11 GI Bill beneficiary is made whole based on the rates established under the Colmery Act. We have taken significant steps to ensure there is broad awareness and understanding of our actions to date. VA executed a comprehensive communications and training campaign to schools, Veterans Service Organizations, state approving agencies, students, beneficiaries, and other stakeholders to regularly provide updates and seek input on VA activities and progress. During the COVID-19 pandemic, VA is working to ensure that Veterans whose education has been impacted by the COVID-19 environment are not being unfairly penalized. Before COVID-19, VBA and VA OIT had been working toward modernizing education benefits IT systems; this effort allows VBA to continue supporting Veterans' educational needs during the pandemic and continue modernization efforts thereafter.

Appeals Modernization

One year after the successful implementation of the Veterans Appeals Improvement and Modernization Act (AMA), VA is encouraged by an active business transformation that is improving Veterans' appeals experience. AMA is transforming VA's complex and lengthy appeals process into one that is simple, timely, and fair to Veterans and that ultimately gives Veterans choice, control, and clarity in the claims and appeals processes. VA is leveraging its telehealth technology to enable tele-hearings, which allow BVA to hold virtual appeals hearings. VA OIT has also significantly expanded its remote access bandwidth, allowing VBA employees to continue business operations remotely and remain efficient during the COVID-19 pandemic. The FY 2021 request of $198.0 million for the Board of Veterans' Appeals (the Board) is $24 million above the FY 2020 enacted budget and will sustain approximately 1,161 FTE. This Budget would prioritize the resolution of legacy appeals at the Board while simultaneously adjudicating appeals under AMA. In addition to adjudicating appeals and claims under AMA, addressing pending legacy appeals will continue to be a priority for VA in FY 2020 and FY 2021. In October, VA finalized an enterprise plan to resolve non-remand legacy appeals by the end of calendar year 2022 and continues to stay on track despite COVID-19. The Board has moved swiftly in the face of COVID-19 to mitigate the substantial impact from the suspension of in person hearings since mid-March. Moving to virtual hearings was the only viable strategy to safely serve Veterans during this pandemic. Between March 24th and May 29th, the Board conducted 789 virtual hearings, and has conducted over 1,000 virtual hearings overall. I am proud of the work being done at VA to make sure those Veterans waiting the longest for a decision get their results.

Business Transformation

Business transformation continues to be central to my focus and is essential for the Department to move beyond compartmentalization of the past and empower our employees serving Veterans in the field to provide world-class customer service. This

means reforming the systems responsible for claims and appeals, GI Bill benefits, human resources, financial and acquisition management, supply chain management, and construction.

Electronic Health Record Modernization

In 2018, VA awarded Cerner Government Services, Inc. a 10-year contract to acquire the same EHR solution being deployed by DoD, which will enable seamless sharing of health information, improve care delivery and coordination, and provide clinicians with data and tools that support patient safety. With the support of Congress, VA's Office of Electronic Health Record Modernization (OEHRM) has made significant strides toward CSS Go-Live in Columbus, Ohio and at our initial operating capability sites in the Pacific Northwest.

While maintaining a non-intrusive posture, amid COVID-19, OEHRM continues to advance the EHRM mission to the greatest extent possible through virtual meetings and activities. OEHRM is continuing design and configuration efforts for additional capabilities that will provide greater functionality for Veterans and end-users at Go-Live. The EHR national standard design and build reached over 99% completion toward meeting the needs of clinicians who require training for the new system. Progress continues toward completing the build of the full EHR solution at the VA Puget Sound Health Care System. Additionally, OEHRM has also made substantial progress with the interfaces to support the EHRM effort. OEHRM completed interface design, build, connectivity and technical testing for all 73 interfaces required to support Go-Live for VA's new EHR solution. Design and connectivity efforts for interface projects to support additional capabilities have been initiated and are progressing toward technical testing.

When facility access is permitted, OEHRM is prepared to advance preparations for the CSS implementation in Columbus, OH and continue the EHRM effort in the Pacific Northwest. OEHRM has prepared drop-in reengagement strategies to continue end user training and implementation efforts at both facilities when determined safe for teams to reengage staff.

The 2021 Budget includes $2.6 billion to continue VA's efforts to implement a longitudinal health record and to ensure interoperability with DoD. This request provides necessary resources for full deployment of VA's new EHR solution at the remaining sites in VISN 20 and VISN 22. Additionally, it partially funds the concurrent deployment of waves comprised of sites in VISNs 7 and 21. VA's new EHR solution will be deployed at VAMCs, as well as associated clinics, Vet Centers, mobile units, and ancillary facilities.

Information Technology Modernization

The 2021 Budget of $4.9 billion continues to invest in the Office of Information and Technology (OIT) modernization effort, enabling us to streamline VA efforts to operate more effectively and decrease our spending while increasing the services we

provide. OIT delivers the necessary technology and expertise that supports Veterans and their families through effective communication and management of people, technology, business requirements, and financial processes. During the COVID-19 pandemic, VA OIT rapidly scaled bandwidth and capacity to enable the Department's remote workforce. In addition to expanding bandwidth, VA OIT migrated teleconferencing capabilities and telehealth/tele-hearing systems to the cloud, increasing bandwidth and call quality and performance. Funding from the CARES Act to sustain this work does not expire until September 2021.

The requested $496 million in technology development funding will be dedicated to specific modernization efforts to support major initiatives such as the VA MISSION Act, the Colmery Act, BWN, Defense Medical Logistics Standard Support (DMLSS), and the Financial Management Business Transformation (FMBT). The Budget also invests $341 million for information security to protect Veterans' and employees' information.

The 2021 OIT Budget includes $250 million for the Infrastructure Readiness Program (IRP) to guide the ongoing refresh and replacement of the IT Infrastructure resources that sustain all VA IT operations. IRP identifies the current state of the IT Infrastructure and provides analysis for the strategy to refresh and modernize IT Infrastructure assets based on equipment age, expiration of warranty, support limitations, lifecycle estimates, business requirements, technology roadmap, financial planning and policy changes.

Financial Management Business Transformation

VA's financial management system for essential accounting and financial activities is more than 30 years old and is growing more obsolete by the day. VA established the FMBT program to achieve VA's goal of modernizing its financial and acquisition management systems. In support of the FMBT program, the 2021 Budget requests a total of $221 million for FMBT, including $111.1 million in IT funds and General Administration funding of $13.9 million. FMBT will leverage the Franchise Fund to bill costs to the Administrations and Staff Offices when the Franchise Fund sells non-IT services to these customers. Additionally, FMBT is leveraging the Supply Fund for costs associated with implementing the acquisition community. Despite the challenges posed by the ongoing pandemic, FMBT has leveraged its Agile program framework to continue moving forward with testing and training activities in this new operating environment. To accommodate the needs of National Cemetery Administration (NCA) field workers during the pandemic and to ensure workforce readiness for the new system, the NCA deployment has been moved to November 2020. This will be followed by the phased implementation of Veterans Benefits Administration (VBA) General Operating Expenses (GOE) in February and May 2021.

Supply Chain Modernization and Defense Medical Logistics Standard Support (DMLSS)

VA's request includes $111.5 million in the Information Technology account for modernizing VA's Supply Chain Management. VA is embarking on a supply chain

transformation program designed to build an efficient and effective medical supply chain to maximize value to clinical customers and deliver real-time analytics capability to support fast and accurate enterprise decision making.

VA's effort will address people, training, processes, data, and automated systems. To achieve greater efficiency, VA will strengthen its long-standing relationships with DoD by leveraging expertise to modernize VA's supply chain operations, while allowing VA to remain fully committed to providing quality health care.

Through this collaboration with DoD, VA will transition to DMLSS, on an enterprise-wide basis to replace VA's existing inventory system. VA's existing legacy system faces numerous challenges and is not equipped to address the complexity of decision-making and integration required across functions, such as acquisition, medical supplies and equipment, medical maintenance, property accountability, facility maintenance and construction. VA's implementation of the DMLSS solution will ensure that the right products are delivered to the right places at the right time, while providing the best value to the government and taxpayers.

VA is piloting DMLSS at the James A. Lovell Federal Health Care Center and VA's initial EHR sites in Spokane and Seattle to analyze VA enterprise-wide application. In DMLSS, VA is leveraging a proven system that DoD has developed, tested, and implemented, and interfaced with DoD's EHR.

Infrastructure Improvements and Streamlining

In FY 2021, VA will continue improving its infrastructure and provide for expansion of health care, burial, and benefits services where needed most. The request includes $1.4 billion in Major Construction funding, as well as $400 million in Minor Construction to fund VA's highest priority infrastructure projects. These funding levels are consistent with our requests in recent years and represent a combined 8.5 percent increase for Major Construction and Minor Construction funding over the FY 2020 appropriation.

Major and Minor Construction

This funding supports major medical facility projects including providing the final funding required to complete projects in Tacoma, WA – American Lake Construction of New Specialty Care Building 201, and Long Beach, CA – Mental Health and Community Living Center. The request also includes continued funding for ongoing major medical projects at Canandaigua, NY – Construction and Renovation; Alameda, CA – Community Based Outpatient Clinic & National Cemetery; San Diego, CA – Spinal Cord Injury and Seismic Corrections; Livermore, CA – Realignment and Closure of the Livermore Campus; and Dallas, TX – Spinal Cord Injury Center. The request also includes funding to construct an inpatient facility in Tulsa, OK, which will be VA's second project under the authorities provided in the Communities Helping Invest through Property and Improvements Needed for Veterans Act of 2016, also referred to as CHIP

IN. The potential project will include both VA's contribution and resources from a partner who will construct a health care facility for Veterans to be donated to VA upon completion.

The FY 2021 request includes funding for national cemetery expansion and improvement projects in San Antonio, TX, and San Diego, CA. The FY 2021 Budget provides funds for the continued support of major construction program including the seismic initiative that was implemented in 2019 to address VA's highest priority facilities in need of seismic repairs and upgrades.

The request also includes $400 million in minor construction funds that will be used to expand health care, burial, and benefits services for Veterans. The minor construction request includes funding for 37 newly identified projects as well as existing partially funded projects.

Leasing

VA is also requesting authorization of thirteen major medical leases in 2021 to ensure access to health care is available in those areas. The 2021 request includes major medical facility leases that VA previously submitted for Congressional authorization in FY 2019 and FY 2020. These leases include new leases totaling $88 million and 371,051 net usable square feet (NUSF) in Columbia, MO; Hampton, VA; Lawrence, IN; and Salt Lake City, UT; and replacement leases totaling $187 million and 849,428 NUSF in Atlanta, GA; Baltimore, MD; Baton Rouge, LA; Beaufort, SC; Beaumont, TX; Jacksonville, NC; Nashville, TN; Plano, TX, and Prince George's County, MD. VA is requesting funding of $1.054 billion to support ongoing leases and delivery of additional leased facilities during the year. These new and ongoing leases represent over 1.2 million square feet of leased space providing state of the art care for our Nation's Veterans.

Repurposing or Disposing Vacant Facilities

To maximize resources for Veterans, VA repurposed or disposed of 196 of the 430 vacant or mostly vacant buildings since June 2017 resulting in an estimated $4.5 million in annual operations and maintenance cost avoidance. Due diligence efforts (environmental/historic) for the remaining buildings are substantially complete, allowing them to proceed through the final disposal or reuse process. VA continues to identify additional vacant buildings for disposal or reuse in order to continue to maximize resources and save taxpayer dollars.

Customer Service

As I have described in past testimony, my prime directive is customer service. In order to sustain VA's commitment to customer experience I will be requesting in FY 2021 a shift from a reimbursable authority (RA) funding model to a hybrid RA and budget authority (BA) model for our Veterans Experience Office (VEO). The FY 2021

request is for $11.5 million in direct BA funding. This strategic shift in VEO's budget model will highlight your commitment and VA's commitment to customer service and the institutionalization of customer experience capabilities within the Department now and in the future. Veterans, their families, caregivers, and survivors deserve nothing less than to know that VA is prioritizing their experiences as a core part of the business. The results and impact of VEO are showing. Veteran trust in VA has increased by 25 percent since 2016 and now stands at a historic high of 80 percent. Veteran trust in outpatient healthcare has also increased from a score of 85 percent in 2017, when we first began to measure outpatient trust to a current score of 89 percent. In the last year, Veteran satisfaction with the redesigned VA.gov Web site has increased by 9 percent using Veteran feedback to improve the site – proof positive that when the Department employs VEO capabilities and practices, it produces better results for Veterans, their families, caregivers, and survivors. VEO is also driving the personalization aspect of customer experience by leveraging business processes and integrated technology solutions for Veterans and their families to make their online and telephonic interactions with VA easier and on par with industry. From their first interaction with VA, customers are "known" because of an integrated VA Profile, a data management initiative that synchronizes Veteran data across the VA's systems, thereby creating a comprehensive Veteran customer profile. An accurate customer profile synchronized across multiple systems is significant, as more than a half million Veterans update their contact information with VA each month; now, they do not have to provide the same information each time they contact VA and VA employees can better focus their time on serving Veterans' needs. VA Profile has already made more than 5.7 million contact information updates.

National Cemetery Administration

The President's FY 2021 Budget positions NCA to meet Veterans' emerging burial and memorial needs through the continued implementation of its key priorities: Preserving the Legacy: Ensuring "No Veteran Ever Dies"; Providing Access and Choosing VA; and Partnering to Serve Veterans. The 2021 Budget includes $360 million for NCA's operations and maintenance account, an increase of $32 million (9.8 percent) over the FY 2020 level. This request will fund the 2,085 FTE employees needed to meet NCA's increasing workload and expansion of services, while maintaining our reputation as a world-class service provider. In 2019, NCA achieved an American Customer Satisfaction Index score of 97, the highest result ever achieved for any organization in either the public or private sector. This ranking is the seventh consecutive time NCA received the top rating among participating organizations. The 2021 Budget will allow us to build upon this unprecedented record of success.

In FY 2021, NCA will inter an estimated 137,600 Veterans and eligible family members and care for over 4 million gravesites at 156 National Cemeteries, which includes 11 cemeteries being transferred from the Department of the Army, and 33 soldiers' lots and monument sites. NCA will continue to memorialize Veterans by providing an estimated 360,000 headstones/markers and distributing 630,600 Presidential Memorial Certificates. NCA will also continue efforts to modernize

Veterans' memorialization through the Veterans Legacy Program and Veterans Legacy Memorial (VLM). In 2021, NCA will again partner with universities and communities to tell the stories of Veterans buried in VA national cemeteries. In addition to these partnerships, NCA will continue the roll out of VLM, a public memorial platform that shares Veteran-related content with the general public.

VA is committed to investing in NCA's infrastructure, particularly to keep existing National Cemeteries open and to construct new cemeteries consistent with existing burial policies. NCA is amid the largest expansion of the cemetery system since the Civil War. NCA will establish 18 new national cemeteries across the country, including rural and urban locations. The 2021 Budget includes operations and maintenance funding to continue activation of new cemeteries that are open for burials. The FY 2021 request also includes $94 million in major construction funds for two gravesite expansion projects (Fort Sam Houston in San Antonio, TX and Miramar, CA) and $86 million in minor construction funds for gravesite expansion and columbaria projects to keep existing national cemeteries open, address infrastructure deficiencies and other requirements necessary to support national cemetery operations.

The Budget request also includes $45 million for the Veteran Cemetery Grant Program to continue important partnerships with States and tribal organizations. Upon completion of these expansion projects, and the opening of new national, State and tribal cemeteries, nearly 95 percent of the total Veteran population—about 20 million Veterans—will have access to a burial option in a national or grant-funded Veterans cemetery within 75 miles of their homes.

Accountability

The total request for the Office of Accountability and Whistleblower Protection (OAWP) in FY 2021 is $26.5 million, which includes funding for 125 FTE employees. This is an additional $4.3 million, or 18 percent over the FY 2020 appropriation and includes funding for an additional 11 FTEs. This funding level will enable OAWP to implement the oversight and compliance requirements of the VA Accountability and Whistleblower Protection Act of 2017 and conduct thorough and timely investigations into whistleblower disclosures, allegations of senior leader misconduct and poor performance, and whistleblower retaliation. In FY 2019, OAWP received 2,951 submissions, directly conducted approximately 165 investigations, and monitored approximately 593 investigations that were referred out for investigation to VA Administrations and staff offices, as required by law. These efforts are part of VA's effort to build public trust and confidence in the entire VA system and are critical to our transformation.

The FY 2021 Budget also requests $228 million for the Office of the Inspector General (OIG), an $18 million increase over the 2020 enacted level, for 1,048 FTEs in 2021 to support essential oversight of VA's programs and operations through independent audits, inspections, reviews, and investigations; and for the timely detection and deterrence of fraud, waste, and abuse. Additional resources will be used

to enhance oversight in program areas that are vital to Veterans and taxpayers, particularly implementation of the VA MISSION Act and the ongoing EHR modernization effort. To that end, OIG will significantly expand oversight of community care, including ongoing efforts to detect and deter health care fraud, financial stewardship, and procurement.

Conclusion

Thank you for the opportunity to appear before you today to address our FY 2021 Budget and FY 2022 AA Budget request. The resources requested in this budget will ensure VA remains on track to meet Congressional intent to implement the VA MISSION Act and continue to optimize care within VHA.

Mr. Chairman, I look forward to working with you and this Committee. I am eager to continue building on the successes we have had so far and to continue to fulfill the President's promise to provide care to Veterans when and where they need it. There is significant work ahead of us and we look forward to building on our reform agenda and delivering an integrated VA that is agile, adaptive, and delivers on our promises to America's Veterans.

JOINT STATEMENT OF
THE CO-AUTHORS OF *THE INDEPENDENT BUDGET*:
DISABLED AMERICAN VETERANS
PARALYZED VETERANS OF AMERICA
VETERANS OF FOREIGN WARS
BEFORE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
WITH RESPECT TO

"U.S. Department of Veterans Affairs Budget Request for Fiscal Year 2021, Advance Appropriations for Fiscal Year 2022 and the Fiscal Year 2022 Supplemental Funding Under P.L. 116-136, the CARES Act"

JUNE 3, 2020

Chairman Moran, Ranking Member Tester, and members of the committee, the co-authors of *The Independent Budget* (*IB*)—DAV (Disabled American Veterans), Paralyzed Veterans of America (PVA), and Veterans of Foreign Wars (VFW) — are pleased to present our views regarding the President's fiscal year (FY) 2021 funding request for the Department of Veterans Affairs (VA), including advance appropriations for FY 2022 as well as the supplemental funds under the CARES Act.

Earlier this year, and prior to the Administration's budget request, the *IB* released its comprehensive VA budget recommendations for all discretionary programs for FY 2021, as well as advance appropriations recommendations for medical care accounts for FY 2022.[1] The

[1] The full *IB* budget report addressing all aspects of discretionary funding for VA can be downloaded at www.independentbudget.org.

recommendations include funding to implement the VA MISSION Act of 2018, Public Law (P.L.) 115-182, and other reform efforts.

Since the publication of the IB's Budget Report, the coronavirus pandemic has fundamentally changed our lives and the institutions we rely upon. We have learned during this crisis that the private health care system does not have excess nor surge capacity sufficient to meet the continuing medical needs of veterans, further emphasizing the importance of maintaining a robust VA health care system as the primary provider of care for enrolled veterans. As a major national health care provider with a contingency mission to assist federal agencies in times of national emergencies, ensuring adequate funding for VA is even more paramount.

We are pleased that the CARES Act (P.L. 116-136) provided almost $20 billion for VA to meet the significant needs of veterans emerging due to COVID-19. We hope that it is clearly understood, however, that this supplemental funding is to address new and unanticipated COVID-related needs VA has and will have over the coming year for additional staff, equipment and supplies, above and beyond the levels already projected. It will also be used to ensure certain groups of veterans will not be financially devastated obtaining preventive or emergency services during the COVID-19 emergency, as well as the needs of homeless veterans who may be at higher risk of contracting the virus. There may also be additional funding necessary to address infrastructure needs allowing VA to improve infection control by increasing the number of private rooms available, improve air flow and ventilation, and take other measures to ensure veterans and staff do not become infected.

In addition, there are a number of other critical VA priorities that require significant funding increases for FY 2021 to ensure veterans have timely access to high quality health care. Congress must continue to support VA's efforts to develop a single electronic health record (EHR) and modernize its health data sharing capability to securely exchange records with community health care partners. New investment in VA's research programs are essential for delivering safe and effective health care in the future, a vital role highlighted by the coronavirus pandemic facing veterans and the nation. VA also requires significantly increased appropriations to repair, replace, realign and expand its infrastructure in some areas, which unfortunately has been neglected for years. In fact, VA recently testified it will need at least $60 billion over the next five years to address its infrastructure backlog and to provide space for the tens of thousands of new health care professionals VA requires, including those who were newly hired in response to the pandemic.

It is our understanding that the overall increase in non-defense discretionary spending allowed under existing budget caps for FY 2021 is only about $5 billion dollars; however, the enacted FY 2021 advance appropriation increase for VA is already more than $8 billion, which is not even enough to cover all of the new requirements created by the VA MISSION Act. This landmark legislation, which was signed into law after the current budget caps were adopted, creates a new VA community care program, expands VA's internal capacity to provide health care, enhances VA's ability to recruit, hire and retain medical personnel; will review, realign and modernize VA's health care infrastructure; and will extend eligibility to VA's comprehensive caregiver assistance

program to family caregivers of all severely disabled veterans. While VA has implemented many sections of the law, the true and full cost of all these reforms is just starting to phase in now, with large increases coming in FY 2021.

Unfortunately, the existing budget caps for FY 2021 did not contemplate all of the new and increased costs associated with the VA MISSION Act, and we are concerned that unless an agreement is reached to alleviate the budget cap pressure on VA's FY 2021 appropriations, veterans programs and services could be negatively impacted. Congress must take action to ensure VA is fully funded through the appropriations process, including consideration of designating some of the funding increases as emergency spending, and must not allow any VA funding to be subject to sequestration or other budget enforcement mechanisms.

As noted above, the IB's FY 2021 Budget Report (attached) contains our full budget recommendations, which are summarized below.

Independent Budget Recommendation for FY 2021 and FY 2022—The *IB* recommends $114.8 billion in total discretionary budget authority for the VA. This recommendation is $4.4 billion more than the Administration's request and an 18% increase over FY 2020. After reviewing the Administration's budget request for VA, which provides a 13% increase, we believe the request falls short of meeting the needs of America's veterans in light of the requirements of the VA MISSON Act, increasing need for medical care, claims and appeals processing, information technology (IT) modernization and construction needs.

The Administration's FY 2021 request for all VA medical care of approximately $95.6 billion is $2.8 billion less than the *IB* estimates is necessary to fully meet the demand by veterans for health care during the fiscal year. For FY 2021, the *IB* recommends approximately $98.4 billion in total medical care funding and approximately $100.6 billion for FY 2022. This recommendation reflects the necessary adjustments to the baseline for all Medical Care program funding of the preceding fiscal year, increases based on new and existing workload, and the 3.1% federal pay adjustment, among other things. Our recommendation did not assume any funds remaining in the Veterans Choice Fund established by section 802 of P.L. 113-146, the Veterans Access, Choice, and Accountability Act of 2014 (VACAA) based on P.L. 116-94, the Further Consolidated Appropriations Act, 2020, and subsequent appropriations for the section 802 account.

Medical Services—For FY 2021, the *IB* recommends $64.4 billion for VA Medical Services. This recommendation reflects multiple components including the current services estimate, the increase in patient workload, and additional medical care program costs:

- The current services estimate reflects the impact of projected uncontrollable inflation on the cost to provide services to veterans currently using the system. This estimate also assumes a 3.1% increase for pay and benefits across the board for all VA employees in FY 2021.

- Our estimate of growth in patient workload is based on a projected increase of approximately 65,000 new unique patients. These patients include priority group 1–8

veterans and covered non-veterans. We estimate the cost of these new unique patients to be approximately $991 million.

- The *IB* believes that there are additional projected medical program funding needs for VA totaling over $2.1 billion. Specifically, an additional $328 million to provide for more centralized prosthetics funding (based on actual expenditures and projections from the VA's Prosthetics and Sensory Aids Service). $200 million to expand and improve services for women veterans. $20 million to support VA's authority for reproductive services including in vitro fertilization (IVF). $779 million to implement eligibility expansion of VA's comprehensive caregiver support program. $776 million to close the reported vacancies for both outpatient mental health and Patient Aligned Care Team (PACT) by 10%.

The Administration's FY 2021 budget request for VA Medical Services, including collections of $60.4 billion, is approximately $4.0 billion below the *IB* recommendation. Although the Administration's request reflects an apparent increase of 10% over FY 2020 funding levels, the *IB* believes that when taking into account the increased cost to maintain current services and anticipated increases in workload, as well as increased costs inside VA due to the VA MISSION Act, that increase becomes a shortfall. Of great concern to our members is the timeline Congress set out in the VA MISSION Act for expanding its comprehensive caregiver support program has clearly not been met. The delay in certifying the IT solution to support expansion of the caregiver program and VA's failure to timely publish a Notice of Proposed Rulemaking raises troubling concerns about VA's ability to fully implement the caregiver expansion. Severely injured World War II, Korean War and Vietnam War veterans and their family caregivers have waited nearly a decade for equal treatment, and it is simply unacceptable to ask them to wait longer.

In terms of funding, the Administration's FY 2021 request included approximately $1.2 billion for VA's comprehensive caregiver support program. Because this request represents an overall increase of $485 million over FY 2020, it is noteworthy that $650 million is to implement the eligibility expansion required under the VA MISSION Act; thus, we are concerned this request assumes a reduction in the number of existing program participants—approximately 20,000 approved family caregivers. The *IB* recommends an additional $779 million for FY 2021 due in large part to the phase-one expansion scheduled towards the end of FY 2020 with only a small portion of the expansion cost absorbed in FY 2020. The *IB's* recommendation is based on the Congressional Budget Office estimate for preparing the program, including increased staffing and IT needs, and the beginning of the first phase of expansion. To continue the expansion, the *IB* recommends $1.4 billion for FY 2022.

Medical Community Care—The *IB* recommends $18.2 billion for this account for FY 2021, which includes the growth in current services. We note the volatility in obligations within this account particularly for contractual services, for which most obligated funds are spent. In addition, our recommendation does not assume any funds remaining in the Veterans Choice Fund established by section 802 of P.L. 113-146, the Veterans Access, Choice, and Accountability Act of 2014 (VACAA) based on P.L. 116-94, the Further Consolidated

Appropriations Act, 2020. For FY 2022, the *IB* recommends $18.7 billion for Medical Community Care.

The Administration's FY 2021 budget authority request for Medical Community Care of $20.4 billion is comprised of a $3.2 billion increase over FY 2020 funding, an estimated increase of $247 million in medical community care collections from $537 million to $784 million, and $1.1 billion remaining in the Veterans Choice Fund account. We have serious doubts whether projected actual spending will converge given the volatility in obligations within this account, the transfer of administrative responsibilities for certain regional networks and provider coverage, and new responsibilities VA is assuming under the new Veterans Community Care Program. Most concerning to the *IB* is VA's proposal to increase non-VA care by nearly 25% next fiscal year compared to just over a 10% funding increase for care provided directly by VA.

Medical and Prosthetic Research—The Administration's request of $787 million is nearly $73 million below the *IB* recommendation of $860 million. The request represents a 2% cut, at a time when medical research inflation is increasing by more than 2%. The VA Medical and Prosthetic Research program is widely acknowledged as a success, with direct and significant contributions to improved care for veterans and an elevated standard of care for all Americans. This research program is also an important tool in VA's recruitment and retention of health care professionals and clinician-scientists to serve our nation's veterans. This reduction would diminish VA's ability to provide the most advanced treatments available to injured and ill veterans in the future, one of VA's core missions.

The COVID-19 pandemic has had a significant impact on the research community. The FY 2020 appropriations bill included $50 million in rescissions from the Medical and Prosthetic Research Program. This rescission not only impedes VA research in all priority areas, including veteran suicide prevention, chronic pain, and post-traumatic stress disorder (PTSD), but is also especially detrimental coming just months before the nation began its fight against the relentless coronavirus pandemic. To address immediate and unexpected COVID-19-related impacts, we recommend at least an additional $50 million for the VA research program through future COVID-19 supplemental funding bills to support new VA research projects and clinical trials designed specifically to address the effects of COVID-19 on the veteran population. With the number of documented COVID-19 cases to date, it is critical that the VA research program is equipped to support front line research efforts to protect a veteran population that is disproportionately older and suffers from preexisting conditions. Thus, we urge appropriators to provide at least an additional $50 million in supplemental funding to directly support VA's COVID-19 response efforts and maintain a robust budget trajectory for VA research in FY 2021 to support continued momentum of all research efforts.

Pandemic-Related Funding—The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), P.L. 116-136) provided VA $19.6 billion in emergency supplemental funding to combat the spread and treat the victims of the COVID-19 virus. Most of the money went directly to the Veterans Health Administration as follows:

General Operating Expenses - $13M
Medical Services - $14.4B

Medical Community Care - $2.1B
Medical Support and Compliance - $100M
Medical Facilities - $606M
General Administration - $6M
IT Systems - $2.2B
Grants for Construction of State Extended Care Facilities - $150M

This supplemental funding was intended to provide essential medical services, including vital medical and protective equipment, testing kits, personal protective equipment (PPE), and medical supplies to support the growing demand for health care services at VA facilities and through telehealth services. Other provisions in the bill required VA to provide PPE to all home health care workers serving veterans at home and in the community and to cover additional pay for VA staff working overtime during the COVID-19 pandemic.

In a House Appropriations Subcommittee hearing on May 28, VA reported that it had only obligated $2.3 billion of the money it received to fight the coronavirus outbreak. It is unclear what these funds were used for since information regarding these expenditures has not been made publicly available. In his testimony before the Subcommittee, VA Secretary Robert Wilkie expressed confidence that the full amount that Congress appropriated would be used to cover COVID-19 related expenses to include combating a potential "second wave" of the virus in the fall. The *IB* expects the entire allocation of emergency funding will be subjected to the normal budgetary oversight processes to ensure it is spent as Congress intended. At the same time, the *IB* cautions against incorporating any part of emergency funding into the department's annual (regular) allocation of funds. The pandemic placed additional burdens on the department that must be fully funded above and beyond the normal budgetary needs.

Vocational Rehabilitation and Employment (VR&E).—This program was authorized to hire an additional 174 FTEs in FY 2019 and implemented workforce increases and tech modernization. In order to ensure the 1 to 125 ratio is maintained nationally and even within each VA regional office or region, for FY 2021, the *IB* recommends $17.2 million for 156 FTE for VR&E, 87% of which are Vocational Rehabilitation Counselors (VRCs). As recently reported, VRCs can spend 60% of their time with administrative functions, thus necessitating the addition of administrative staff.

However, in the recent Administration's budget request, it was indicated that with guidance in the FY 2020 Appropriations Act, VBA will also reallocate 166 FTE to VR&E, a result of decreased resources required to process legacy appeals, to support anticipated program growth and maintain the 1:125 counselor-to-veteran ratio at the station level. To be clear, the 1:125 ratio is based on VRCs and not administrative staff. The Administration's proposal would not increase the number of VRCs, only administrative staff. While we agree that an increase in administrative staff is warranted, the number of FTE for VRCs needs to addressed as well.

Board of Veterans' Appeals (BVA).—For FY 2021, the *IB* recommends approximately $218 million for the BVA, an increase of approximately $36 million over the estimated FY 2020 appropriations level, which reflects funding for current services with increases for inflation and federal pay raises and an additional 100 FTE.

In February 2019, the Veterans Appeals Improvement and Modernization Act (AMA), P.L. 115–55, took full effect, making significant changes in how veterans appeal VBA claims decisions, both within VBA and at the Board of Veterans' Appeals (BVA). There are currently 17,000 pending AMA hearings with the Board and 59,000 pending legacy hearings, for a total of 66,000 pending hearings. In FY 2019, BVA conducted a record number of 22,743 hearings, a 38% increase over the prior year. Even at that rate, it will take three years to hold all hearings for legacy appeals and yet not address the current 17,000 pending AMA appeals with requested hearings, not to mention the additional AMA appeals received during those three years.

The Administration's budget request would not increase staffing at the Board. It indicates VA expects to lose 29 FTE, based on attrition, in FY 2021. However, as the number of backlog hearings has not drastically been reduced and many of the legacy hearings have been pending for years, we are recommending an increase of 100 FTE for the Board to address the 66,000 pending hearings.

Information Technology (IT). — VA relies extensively on information technology to meet day-to-day operational needs. At Congress' direction, over a decade ago, VA centralized all IT budget authority, management, and development under a chief information officer (CIO). It is now one of the few agencies of its size with a CIO that has complete IT authority affecting the entire organization. Centralization mandated fiscal discipline, security, standardization, and interoperability. Yet little oversight, if any, has been conducted of this organization since centralization and its performance in supporting VA's statutory missions, including benefits and health care delivery, research, and education and training of health professions. For FY 2021, the IBVSOs recommend approximately $4.3 billion for the administration of the VA's IT program to meet the need to sustain VistA for an estimated 7–10 years after initial operating capabilities are attained at initial sites for replacing VistA.

For several years, the VA has indicated the development of IT applications remains under VA's three separate administrations — VBA, VHA, and the National Cemetery Administration (NCA); however, the development funding has been in decline over the last five years. In nominal dollars since 2014, total development funding has been reduced by over 40% while the overall funding has increased by 6%. We are pleased VA is requesting an increase of $68 million in development activities. The *IB* similarly recommends $150 million, of which $65 million would be provided to VA's Education Services and the remaining $85 million to OIT, to develop an IT system capable of handling today's difficult tasks, and tomorrow's upcoming changes. In addition, we recommend IT development funding of $15 million for FY 2021 for the BVA's Case Flow, which currently does not have all the functionalities needed to replace the legacy Veterans Appeals Control and Locator System (VACOLS).

To support the electronic health record modernization efforts in FY 2021, the *IB* recommends $2.48 billion, which includes $180 million to support accelerated deployment of Cerner Millennium Scheduling System. These amounts are also based on VA's deployment schedule estimating FY 2021 resource needs to complete initial operating capability sites and deployment throughout the remainder of VISN 20 and 22, and initiating deployment in VISN 21.

Capital Infrastructure.—*The Independent Budget* has advocated for a larger Capital Infrastructure budget for the past few years and the COVID-19 crisis has highlighted the need for further resources dedicated to this account. Many of the necessary changes needed due to this health crisis would fall under Minor Construction and Non-Recurring Maintenance (NRM); however, aging major medical facilities needing replacement and upgrades must be taken into consideration as well.

Some of the potential changes needed during and after the COVID-19 crisis include the need for additional treatment space. Facilities are having to reconfigure patient rooms for single occupancy, and expand waiting rooms to be able to separate patients due to social distancing guidelines. Modifications such as these would require an increase in the Minor Construction budget, so as to not use up existing funds for emergency circumstances.

Other issues such as ventilation would require modifications or upgrades to existing systems which could cost VA facilities precious NRM dollars originally allocated to other vital projects. Modifications to HVAC systems to ensure proper circulation and negative air pressure rooms for patients are just some of the changes needed for each facility to safely treat COVID-19 related patients.

During extreme circumstances such as a global pandemic, VA resources are spread thin and multiple deficiencies are spotlighted due to multiple stressors. The need for modern facilities and evolving treatment infrastructure are present now more than ever. The IB is recommending an increase in VA's Capitol Infrastructure budget, in order to maintain what VA has, and expand to meet the ever changing healthcare situation during this crisis.

Construction Programs.—The Administration's FY 2021 request for VA's construction programs of $1.9 billion dollars is a deeply disappointing retreat in funding to maintain VA's aging infrastructure. At the Senate Committee on Veterans' Affairs hearing on March 26, 2019, in response to Senator Manchin's question about VA's "decrease in funding levels for construction programs," Secretary Wilkie stated that he estimates VA will need, "$60 billion over the next five years to come up to speed." This backlog is confirmed by VA's FY 2021 budget submission, which states that VA's, "Long-Range SCIP plan includes 3,595 capital projects that would be necessary to close all currently-identified gaps with an estimated magnitude cost of between $49-$59 billion not including activation costs." However, VA's FY 2021 budget request for major and minor construction combined is just over $1.9 billion, significantly below the true need stated by the Secretary and identified by SCIP. At a time when VA is seeking to expand its capacity by hiring additional doctors, nurses, clinicians and supporting staff, it is absolutely critical that VA continue to invest in the infrastructure necessary for them to care for veterans.

Some major construction projects have been on hold or in the design and development phase for years. Additionally, there are outstanding seismic corrections that must be addressed. Thus, the *IB* recommends $2.7 billion for VA's FY 2021 major construction, over $1.4 billion more than VA's request.

To ensure VA funding keeps pace with all current and future minor construction needs, the *IB* recommends Congress appropriate an additional $760 million in FY 2021 for minor construction projects. It is important to invest heavily in minor construction because these are the types of projects that can be completed faster and have a more immediate impact on services for veterans. VA's FY 2021 request of $400 million is significantly less it has requested in previous years, and will only allow the critical infrastructure backlog to continue to grow.

Non-Recurring Maintenance (NRM) had seemed to slip through the cracks within the construction space in previous years. VA's FY 2021 request of $1.8 billion in budget authority for NRM, however, is a significant increase from previous years. NRM projects are often necessary maintenance that is preventative in nature and saves equipment and facilities from reaching failure points. Heavy investment in NRM is a wise expenditure because spending money to maintain equipment and buildings ensure longevity and costs a fraction of having to replace buildings with new construction. The *IB* is pleased VA has requested to invest in this critical concern.

A congressionally mandated research infrastructure report shows a total cost of $99.5 million in Priority 1 deficiencies having an immediate need for correction within one year, such as correcting life-safety hazards, returning components to normal service or operation, stopping accelerated deterioration, and replacing items that are at or beyond their life cycle. The total cost to correct Priority 1-5 deficiencies is estimated at $207.1 million. Accordingly, the *IB* recommends a minimum of $99.5 million for FY 2021 to correct all Priority 1 deficiencies.

Grants for state extended care facilities, commonly known as state home construction grants, are a critical element of federal support for state veterans' homes. For FY 2021, the *IB* recommends $250 million for grants for state extended care facilities to fund approximately half of the federal share of projects on the FY 2020 VA State Home Construction Grants Priority List for Group 1, those that have already secured their required state matching funds.

National Cemetery Administration.—The *IB* commends the Administration for requesting a $31-million-dollar increase in appropriations for NCA to account for its obligation to manage 156 national cemeteries and to meet a continued increase in demand for burial space which is not expected to peak until 2022. NCA continues to expand and improve the national cemetery system, to include a plan to open additional burial sites in 2021. NCA has also inherited 11 Army post cemeteries which it must perpetually maintain. VA's request of $360 million for NCA operations and maintenance is $24 million more than the *IB* recommendation of $336 million.

Additionally, NCA has undertaken the task of creating a digital memorial page for each veteran interred in a VA national cemetery as part of the Veterans Legacy Memorial. This much needed expansion of the national cemetery system will help to facilitate the projected increase in annual veteran interments and will simultaneously increase the overall number of graves being maintained by NCA to more than 4 million by 2021. The *IB* strongly believe that VA national cemeteries must honor the service of veterans and fully support NCA's National Shrine initiative, which ensures our nation's veterans have a final resting place deserving of their sacrifice to our nation. The *IB* also support NCA's Veterans Legacy Program (VLP), which helps educate America's youth about the history of national cemeteries and the veterans they honor. Recently enacted P.L. 116-107,

which authorizes NCA to provide grants as part of VLP, may enable VA to significantly expand VLP and ensure more veterans can have their stories preserved in perpetuity.

Administration Legislative Proposals.—The IBVSOs strongly oppose four benefit- related legislative proposals included in the budget that would reduce benefits to disabled veterans that were earned through their service:

1. **Effective Date Simplification for Claims for Increased Evaluation:**

VA seeks to amend title 38, United States Code, § 5110(b)(3) to make the date of receipt of a claim the effective date for an increased rating. While VA states this is a simplification of claims for increase, this proposed amendment would take away billions of dollars from veterans by disallowing entitlement to an increased evaluation prior to the date of claim.

Title 38. United States Code, § 5110(b)(3) states, "the effective date of an award for increased compensation shall be the earliest date as of which it is ascertainable that an increase in disability has occurred, if application is received within one year from such date."

For example, if medical evidence establishes entitlement to an increase rating eight months prior to the date the claim for VA benefits was submitted, the effective date for benefits granted will be that date eight months prior. By eliminating this statutory provision, VA would virtually discredit any medical evidence prior to the date of claim on claims for increase and negatively impact effective dates for individual unemployability. Not only would this bear directly on retroactive compensation, this proposal would also confound certain protections and other ancillary benefits based on effective dates.

The Administration's proposal would reduce anticipated disability compensation to veterans by $678 million in 2021, $3.5 billion over five years, and $7.5 billion over 10 years. We strongly oppose this attempt to "simplify" effective dates for claims for increase particularly when the result will be billions of dollars in lost disability compensation for those who were injured or made ill in service.

2. **Limit Disability Evaluations to Criteria within the VA Schedule for Disabilities (VASRD):**

VA seeks to amend title 38, United States Code, § 1155 so that disability evaluations can only be established based on criteria within the VASRD and effectively eliminate extra-schedular consideration.

Extra-schedular cases are not defined by statute but in 38, Code of Federal Regulations, § 3.321(b)(1). It notes that to accord justice to the exceptional case where the schedular evaluation is inadequate to rate a single service-connected disability, an extra-schedular evaluation commensurate with the average impairment of earning capacity due exclusively to the disability is to be considered. The governing norm in these exceptional cases is a finding that application of the regular schedular standards is impractical because the disability is so exceptional or unusual due to such related factors as marked interference with employment or frequent periods of hospitalization.

The United States Court of Appeals for Veterans Claims (Court) has set out a three-part test, based on 38, Code of Federal Regulations, 3.321(b)(1) for determining whether a claimant is entitled to an extra-schedular rating: (1) the established schedular criteria must be inadequate to describe the severity and symptoms of the claimant's disability; (2) the case must present other indicia of an exceptional or unusual disability picture, such as marked interference with employment or frequent periods of hospitalization; and (3) the award of an extra-schedular disability rating must be in the interest of justice. Thun v. Peake, 22 Vet. App. 111 (2008), affd, Thun v. Shinseki, 572 F.3d 1366 (Fed. Cir. 2009).

The VASRD does not contemplate every disease or disability, nor does it provide an evaluation for every set of symptoms and complications caused by each disability. This proposal would eliminate any veteran attempting to be afforded justice for the severity and symptoms of an unusual disability picture that provides marked interference with employment or frequent hospitalizations. This is an attempt to avoid the precedence as established by the Court.

The Administration's proposal would reduce anticipated disability compensation to veterans by $74.7 million in 2021, $1.1 billion over five years, and $4.2 billion over 10 years. We strongly oppose this attempt to "simplify" effective dates for claims for increase particularly when the result will be billions of dollars in lost disability compensation for those who were injured or made ill in service.

We oppose any proposal that would eliminate extra-schedular consideration as it will not consider veterans' with unusual disability pictures based on marked interference with employment or frequent hospitalizations and effectively tip the scales of justice against them.

3. Round-Down of the Computation of the Cost-of-Living Adjustment (COLA) for Service-Connected Compensation and Dependency and Indemnity Compensation (DIC) for Five Years:

In 1990, Congress, in an omnibus reconciliation act, mandated veterans' and survivors' benefit payments be rounded down to the next lower whole dollar. While this policy was initially limited to a few years, Congress continued it until 2014. While not significant at the onset, the overwhelming effect of 24 years of round-down resulted in veterans and their beneficiaries losing billions of dollars.

In the Administration's proposed budget for FY 2020, the Administration sought legislation to round-down the computation of COLA for five years. This would have cost beneficiaries $34 million in 2020, $637 million for five years, and $2 billion over 10 years.

The Administration's proposed budget for FY 2021 is seeking to round-down COLA computations from 2021 to 2026. The cumulative effect of this proposal levies a tax on disabled veterans and their survivors, costing them money each year. When multiplied by the number of disabled veterans and DIC recipients, millions of dollars are siphoned from these deserving individuals annually. All told, the government estimates that it would cost beneficiaries $39 million in 2020 and $677 million for five years and $2.2 billion over 10 years.

Veterans and their survivors rely on their compensation for essential purchases such as food, transportation, rent, and utilities. Any COLA round-down will negatively impact the quality of life for our nation's disabled veterans and their families, and we oppose this and any similar effort. The federal budget should not seek financial savings at the expense of benefits earned by disabled veterans and their families.

4. Elimination of Payment of Benefits to the Estates of Deceased Nehmer Class Members and to the Survivors of Certain Class Members:

VA seeks to amend title 38, United States Code, § 1116 to eliminate payment of benefits to survivors and estates of deceased Nehmer class members. If a Nehmer class member, per 38 Code of Federal Regulations, § 3.816, entitled to retroactive benefits dies prior to receiving such payment, VA is required to pay any unpaid retroactive benefits to the surviving spouse or subsequent family members. This proposed legislation would deny veterans' survivors and families' benefits that would have otherwise been due to their deceased veteran family member as a result of exposure to these toxic chemicals while in service. It is outrageous that the Administration would deny compensation payments due to a surviving spouse. We adamantly oppose this or any similar proposal that may be offered.

The *IB* supports one of VA's legislative proposals regarding VA approved Medical Foster Homes (MFH). This proposal would require the VA to pay for service-connected veterans to reside in VA approved MFHs.

MFHs provide an alternative to long-stay nursing home (NH) care at a much lower cost. The program has already proven to be safe, preferable to veterans, highly veteran-centric, and half the cost to VA compared to NH care. Aligning patient choice with optimal locus of care results in more veterans receiving long-term care in a preferred setting, with substantial reductions in costs to VA. This proposal would require VA to include MFH in the program of extended care services for the provision of care in MFHs for veterans who would otherwise encumber VA with the higher cost of care in NHs.

Many more service-connected veterans referred to or residing in NHs would choose MFH if VA paid the costs for MFH. Instead, they presently defer to NH care due to VA having payment authority to cover NH, while not having payment authority for MFH. As a result of this gap in authority, VA pays more than twice as much for the long-term NH care for many veterans than it would if VA was granted the proposed authority to pay for MFH. This proposal would give veterans in need of NH level care greater choice and ability to reside in a more home-like, safe environment, continue to have VA oversight and monitoring of their care, and preferably age in place in a VA-approved MFH rather than a NH. The proposal does not create authority to cover veterans who reside in assisted living facilities.

MFH promotes veteran-centered care for those service-connected veterans who would otherwise be in a nursing home at VA expense, by honoring their choice of setting without financial penalty for choosing MFH.

Thank you for the opportunity to submit our views on the Administration's budget request for VA. We firmly believe that unless Congress acts to increase VA's funding for FY 2021 and 2022, veterans will be forced to wait longer for benefits and services leaving unfulfilled the promises made to those who have served and sacrificed defending our country.

QUESTIONS AND RESPONSES FOR THE RECORD
Department of Veterans Affairs

Chairman Moran

Question 1. The FY21 request includes $56.6 billion for Medical Services and $18.8 billion for Medical Community Care. When compared to FY20 funding levels, this is an increase of $5.6 billion and $3.8 billion respectively.*

Question 1a. Why are we seeing steady growth for both internal VA medical services and community care?

Response: The main driver for steady cost growth in both internal VA medical services and community care is that workload is growing in both settings, as more Veterans increasingly rely on VA for their care. Much of this growth in reliance results from the MISSION Act, which made care in both settings more appealing by expanding and improving Veterans' options. Although the MISSION Act specifically expanded Veterans' access to and utilization of community care, the MISSION Act also required additional funding for internal VA medical services to complement community care appointments (e.g., pharmacy, prosthetics, beneficiary travel benefits) and to cover growing demand and capacity for in-house care. Both settings were also subject to other non-workload factors associated with growth, including inflation and other health market factors.

Question 1b. Why does the Department continue to request an increase in funding for both internal and community care instead of seeing decreases in either account or any tangible trade-offs?

Response: As addressed in part a, VA is seeing growth in demand for care in both settings, rather than a substitution effect of fixed demand changing care locations. As VA care became more desirable, Veterans with access to Medicare or other health insurance are increasingly using VA for their care.

The number of completed internal outpatient appointments continues to rise by over one million each year. In fiscal year (FY) 19, Veterans Health Administration (VHA) completed 59.9M appointments. In FY18, VHA completed 58.2M appointments.

Question 1c. Of the requested increases to internal and community care, what percentage is related to an increase in the number of veterans served?

Response:

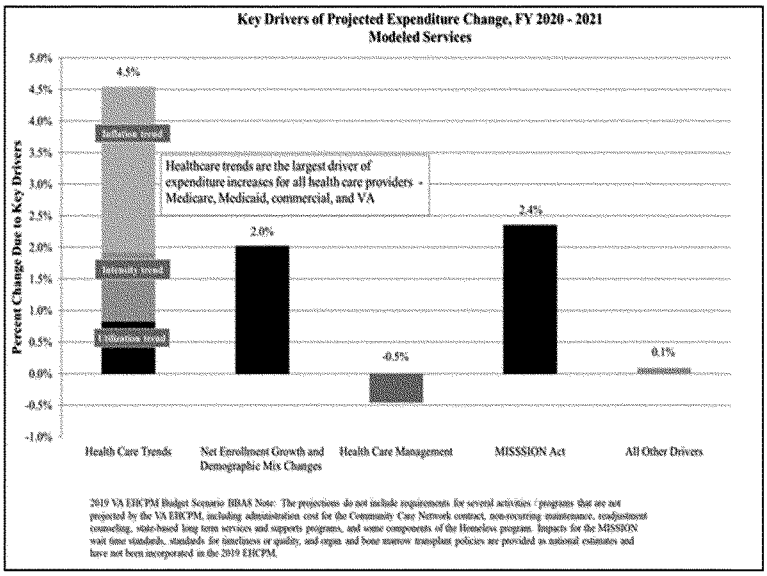
	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Total Veterans	5,959,029	6,033,598	6,075,500	6,133,940	6,212,398
In-House	5,874,385	5,939,528	5,992,853	6,054,557	6,117,278

Community	1,491,149	1,528,622	1,707,503	1,796,037	2,094,903

&Numbers will not add up as Veterans can receive care in both venues.

Question 1d. Of the requested increases to internal and community care, what percentage is due to increased costs of care?

Response: The key drivers relating to the 2021 President's Budget request can be found in the Actuarial Model Projections chapter of the Congressional Budget Justification Volume 2, beginning on page VHA-259. The table below provides the key cost drivers from VHA's Enrollee Health Care Projection Model (EHCPM), which account for over 90% of VHA's Medical Care appropriation request.



Question 2. To reduce risk of patient exposure to COVID-19, the Department facilitated a decrease in community care for routine appointments and increased its use of telehealth services. Since the outbreak, community care referrals have decreased; by over 70 percent in some regions.*

Question 2a. Congress passed the CARES Act on March 27, 2020 to provide supplemental appropriations for FY20, including an appropriation of $2.1 billion for community care. How much of the $2.1 billion has been spent based on expected and actual obligations in community care?

Response: As of the end of the month of June, VA obligated just under $30 million of the $2.1 billion provided in the CARES Act. VA is allocating based on community care related to Veteran COVID needs.

> *Question 2b.* Given the reductions in community care and increases in telehealth services, does the Department expect the cost of community care in FY21 to be different than the budget estimate contained in the FY21 budget? Does the Department expect to update the FY21 community care budget estimate? If so, what is the Department's new FY21 budget estimate?

Response: At this time our investment in telehealth has not changed our budgetary requirements for FY21. VA will continue to monitor and notify Congress should estimates change.

Question 3. The Department's data indicates that 173,721 authorizations, excluding emergency and urgent care, were written for community care from March 24 to April 19, 2020. How many authorizations for community care were provided during this time last year?

Response: During the March 24, 2019 to April 19, 2019 timeframe, VA provided 380,834 authorizations. Additionally, in regard to 2020 authorizations, the latest update reflects 203,870 community care referrals were provided in the same timeframe.

Question 4. The Department's reopening plan indicates that it will schedule community care and virtual care appointments where "clinically appropriate." Who is responsible for determining whether an appointment is clinically appropriate? Is this decision made or influenced by anyone other than the veteran and his clinician? *

Response: As a high reliability organization, VA considers the safety of our Veterans first, in collaboration with the Veteran's preferences and needs as to whether an appointment is appropriate for virtual care or a face-to-face visit. Clinical care delivery is aligned with the Moving Forward Plan risk assessment, the Veteran's unique clinical indications and risks, the type of service or procedure and coordination with the clinical care team.

Decisions on which time-sensitive care to deliver is based on clinician determination of risk by the ordering provider or the receiving specialist reviewing the request.

Question 5. The Department's data indicates that there were over 5.7 million appointment cancellations within its direct system from February 1 to April 7, 2020, which includes outpatient appointments for Primary Care, Mental Health and Specialty Care.

> *Question 5a.* How many appointments were cancelled as of June 3, 2020? How many of those appointments were scheduled to be in the community and how many were internal? For both internal and community care, how many of those appointments were cancelled by the patent? How many of those appointments were cancelled by community care providers?

Response: Cancellation numbers are in Table 1 below for internal appointments. VHA can only pull data for internal cancellations and only identify cancelled by patient for internal cancellations.

Table 1 Internal Appointment Cancellations:

	Cancelled by Clinic	Cancelled by Patient	Cancelled by Clinic or Patient
Feb-FY20	689,966	1,057,547	1,747,513
Mar-FY20	1,668,491	1,494,133	3,162,624
Apr-FY20	2,135,213	1,028,396	3,163,609
May-FY20	1,641,055	605,756	2,246,811
June 1-3rd	254,137	97,223	351,360
Grand Total	6,388,862	4,283,055	10,671,917

Community care appointment cancellation numbers are reflected below in Table 2. Cancellation information is limited and only available for initial appointments when a Veteran or a community provider notifies VA of a cancellation. A distinction cannot be made whether the appointment was cancelled by the patient or the community provider. Follow-up appointment cancellations and other cancellations without notifications are not captured. So, the full volume of cancellations is not reflected in the table.

Table 2 Community Care Appointment Cancellations:

Month	Total # of Appts Cancelled	Total # of Appts Cancelled with a COVID Comment
Feb	33,762	COVID Cancellation Not Tracked in Feb
Mar	62,950	17,111
Apr	49,828	14,588
May	33,411	3,609
June	34,889	908
Grand Total	**214,840**	**36,216**

Question 5b. Will the Department reschedule every cancelled appointment? Does the Department currently have a rescheduling plan? If so, please provide the plan.

Response: No. Reviews by a clinical care team will be executed, and appointments rescheduled as clinically indicated. Some will not be rescheduled because the Veteran either no longer desires the care or will obtain that care in the community.

Yes. In March 2020, VHA devised a plan to instruct facilities on how to convert a face-to-face appointment into a virtual appointment such as a video appointment or telephone appointment for all Veterans as clinically indicated. The process includes cancelling the face to face appointment in order to schedule a virtual appointment. Additionally, VA has identified some Veterans that have no evidence of follow-up by using the appointment cancellation data report, which may include Veterans that no longer desire care or need care. VA currently has the Cancelled Appointment and Consult Management Initiative. VHA will document review and resolution for cancelled appointments that have no other evidence of follow-up. Often schedulers contact Veterans, and this is difficult to see in the data report. VHA has begun to communicate expectations to VA medical centers (VAMCs) and Network Directors.

Question 5c. How many of the 5.7 million cancellations were rescheduled as telehealth appointments during the same three-month period? How many as of June 3, 2020?

Response: *The present report does not do a one to one link to see the conversion of cancelled appointments. However, see table 2 and table 3 below for telehealth numbers.*

Table 2

	All Clinical telehealth visits
FEB-FY20	129,528
MAR-FY20	199,692
April 1st-7th	405,460
Grand Total	734,680

Table 3

	All Clinical telehealth visits
FEB-FY20	129,528
MAR-FY20	199,692
APR-FY20	402,300
MAY-FY20	488,290
June 1st - June 3rd	80,558
Grand Total	1,300,368

Question 5d. How many of the 5.7 million cancellations have been rescheduled in the VA during the same three-month period? How many as of June 3, 2020?

Response: The current scheduling system does not allow us to link cancelled appointments to those that are rescheduled.

> *Question 5e.* How many of the 5.7 million cancellations have been scheduled in the community during the same three-month period? How many as of June 3, 2020?

Response: At this time, VHA is not able to provide this data as there is currently not a data linkage that would allow the two offices to associate an internal cancelled appointment to a community care consult/referral for the same care.

Question 6. In the event that there is a second wave of COVID-19 in the fall,

> *Question 6a.* How will the epidemic affect FY21 funding obligations for care in the VA and in the community?

Response: Between the CARES Act and our 2021 President's Budget request, VA should have resources to meet the need. VA will continue to monitor and notify Congress should estimates change.

> *Question 6b.* Does a shift to telehealth, whether in the VA or in the community, reduce the cost of care, whether in the VA or in the community? If so, what is the reduction in cost?

Response: VA is investing in telehealth capacity because of its potential to provide improved outcomes and Veteran satisfaction more efficiently. However, at this time our investment in telehealth has not changed our budgetary requirements for FY21.

For most community care services, VA reimburses at the applicable Medicare rate published by the Centers for Medicare and Medicaid Services (CMS). For the duration of the public health emergency, CMS has announced that Medicare rates for telehealth services will be the same as in-person rates. So, at this time, there are no changes in cost.

> *Question 6c.* Between telehealth, in-person VA care, and in-person community care, which method of delivery provides the most cost-savings?

Response: VA provides Veterans care in the setting most appropriate to their preferences and their care needs, VA has observed significant cost variance in all three settings.

Question 7. Community Care Network contracts use different access standards than those developed by the VA—which could result in veterans traveling up to 3 hours for community care. Will the department modify those contracts, and does the FY2021 budget request include the necessary funding to modify CCN contracts to include VA access standards?

Response: VA is reviewing Community Care Network (CCN) Region 1-4 contracts to determine the best approach to modify them to meet MISSION Act. It's the VA's intent to bring CCN Region 1-4 contracts into MISSION Act access compliance and ensure our Veterans get the care they need in a timely manner. We continue to work with our contracting partners to reach agreement that will minimize the gaps in available network coverage. One of the challenges faced is that the CCN networks are built upon historical preferences and those have evolved as the new CCN networks are being built. The requirements of the MISSION Act were not

anticipated in the contracts that were awarded to Optum: VA continues to work with Optum to gradually modify the contract to meet those needs while being prudent with the available budget.

VA has built a budget to support the MISSION Action 104 Access standards for all awarded regions

Question 8. In FY11, the budget request for mental health services and suicide prevention programs was $5.2 billion. The FY2021 request is almost double the FY11 level as $10.2 billion.

> *Question 8a.* After 10 years of increasing funding, what is the Department's approach to address mental health and suicide prevention that will be different from the past and yield better outcomes for veterans?

Response: VA has been primarily focused on internal strategies to reach Veterans within our system for suicide prevention. However, VA's current actions and future vision for reducing suicide among all 20 million U.S. Veterans, is to focus our efforts on a comprehensive public health approach, known as Suicide Prevention 2.0 (SP 2.0). This approach combines community-based prevention and clinically-based intervention strategies within every VA healthcare system. SP 2.0 is organized across three domains: universal, which encompasses all Veterans; selective, which targets those at an increased risk of suicide; and indicated, which is a smaller segment of those at a high risk. VHA's community-based prevention strategies address needs at state and local community levels. For state-level prevention, the Office of Mental Health and Suicide Prevention (OMHSP), in collaboration with our partners at the Substance Abuse and Mental Health Services Administration (SAMHSA), is supporting expanding the Governor's Challenges to Prevent Suicide Among Service Members, Veterans, and their Families, where state-level policymakers will partner with local leaders to implement a comprehensive suicide prevention plan, with a goal to invite all 50 states to participate by the end of FY22.

For local community action, OMHSP is supporting expansion across all Veterans Integrated Service Networks (VISNs) of a Community Engagement and Partnerships – Suicide Prevention (CEP-SP) program focused on community coalition-building coupled with targeted outreach and education, as well as the Together With Veterans (TWV) program, a VA Office of Rural Health program focused on empowering and supporting Veteran leadership for suicide prevention. These community-based interventions expand the capacity of VISNs to engage in community-based suicide prevention efforts in their region, thereby reducing population suicide rates among Veterans.

For the clinically-based strategy of SP 2.0, planning is currently underway, in partnership with VA's Clinical Resource Hubs (CRH), to develop and support the delivery via telehealth of evidenced-based interventions for suicide prevention, highlighted in the recently released VA/ Department of Defense (DoD) Clinical Practice Guideline (CPG) on the Assessment and Management of Patients at Risk for Suicide at (https://www.healthquality.va.gov/guidelines/MH/srb/). The initial focus will be on the roll out of Cognitive Behavioral Therapy for Suicide Prevention (CBT-SP) and will move to other therapies such as Problem-Solving Therapy for Suicide Prevention (PST-SP). The CPGs also advise the development of a crisis response plan, or safety planning intervention, for individuals with suicidal ideation and/or a history of suicide attempts. SP 2.0 will include promoting Advanced Safety Planning Intervention (ASPI) in Veterans with suicidal ideation and/or a history of suicide attempts.

SP 2.0 is informed by the evidence supporting suicide prevention interventions and public health approaches. The Center for Disease Control and Prevention (CDC), SAMHSA, and the National Action Alliance for Suicide have all moved toward a public health approach to suicide prevention. The model works to incorporate reaching both Veterans in the community as well as those we currently serve in the VA with innovative community-based prevention strategies combined with strategies with known outcomes for reducing suicide and suicide attempts based upon the recently updated VA-DoD CPGs.

Currently, the National Suicide Prevention Program is working with program evaluation and implementation science experts to design a phased implementation which will allow for assessment of outcomes over time to increase generalizability of findings to both VA and non-VA settings of SP 2.0. A full measurement plan is under development. Unique elements of SP 2.0 utilizing both community prevention and clinical intervention strategies will be studied including such variables as:

- Decrease in Veterans suicides,
- Decrease in Veteran suicide attempts and behaviors,
- Increase state and community coalitions,
- Number of gatekeepers trained in suicide prevention,
- Spread of evidence-based therapies for suicide prevention and upstream risk (insomnia, pain, etc) both within VHA and communities,
- Increased and improved quality of messaging for suicide prevention,
- Number of Veterans identified that were not in VHA care or using benefits now engaged in treatment and/or services

We believe that the advancement of a public health approach to suicide prevention will save lives. These strategies are evidence-based and address gaps in existing VA suicide prevention programs, which have been primarily focused on internal strategies to reach Veterans within our system. By targeting both community prevention and clinical intervention, we improve our ability of reaching all 20 million U.S Veteran, not just those in VA care.

> *Question 8b.* How does the department plan to increase community-based support for veterans, invest in cutting-edge brain and mental health research, and consider innovative new treatment approaches?

Response: As noted in response 8.a. the VA is increasing community-based support through S.P. 2.0 which expands three initiatives for community-based suicide prevention through an integrated model with guidance from the 2018-2028 National Strategy for the Prevention of Veteran Suicide. These programs are currently operating and being expanded in a phased approach over the next 2 years. They include:

- VISN-based Community Engagement and Partnerships for Suicide Prevention (CEP-SP) is focused on enhancing community suicide prevention coalitions for Veteran suicide prevention through the building of new coalitions and supporting the work of existing coalitions whose missions align with Veteran suicide prevention. The first pilot of this program began as a partnership between OMHSP, VISN 23, and academic researchers and implementation specialists from the University of Pittsburgh's Program Evaluation

and Research Unit (PERU). CEP-SP is being expanded to VISNs 4, 9, and 12 in Fiscal Year (FY) 20 with expansion to all VISNs planned through FY21 and FY22.

- Together with Veterans (TWV), a VA Office of Rural Health partnership with VA, focuses on Veteran-to-Veteran coalition-building and Veteran leadership. TWV enhances the capacity of rural and frontier communities' suicide prevention networks through application of four principles: Veteran-led, collaborative, evidence-informed, and community-centered. In 2018, TWV expanded to pilot sites in Montana and North Carolina, developing strong evidence for feasibility, acceptability, reach to large numbers of rural Veterans, and implementation of best practices. TWV is currently expanding to 22-34 new sites nationwide in FY19-FY22.

- The Governor's and Mayor's Challenge supports state leaders in developing and implementing a comprehensive and state-wide suicide prevention plan for reducing suicide among Service Members, Veterans and their Families (SMVF). The Governor's Challenge was launched in 8 states in FY19 and is anticipated to invite 27 states by end of 2020, with all remaining 50 states and territories being invited to participate by the end of FY22.

Investments in cutting-edge brain and mental health research will involve a number of innovative opportunities and pathways that focus specifically on understanding these illnesses and treatment. Among the novel treatment approaches will be efforts to use genetic information for analyses and queries to help identify new targets for drug treatment such as for Post-Traumatic Stress Disorder (PTSD). As soon as it is safe and feasible (considering the COVID-19 pandemic situation), the VA Office of Research and Development will launch a project called Million Veteran Program (MVP)-MIND to directly recruit new mental health patients into the VA MVP, the world largest genomics research cohort. These participants will come from VA's mental health clinics so that individuals with mental health and substance abuse diagnoses will be more fully represented in MVP and provide a larger pool of individual to better understand any relationships between genes and mental health conditions. Other innovative approaches include investments in depression treatment studies, which VA has a long-standing record of accomplishments related to building the evidence base for supporting clinical practice. In addition, the Health Services Research and Development program is working closely with program partners in the VA Office of Mental Health and Suicide Prevention to help implement and evaluate suicide prevention programs such as REACH-VET and Caring Contacts, a program that proactively sends message to keep high-risk Veterans engaged. We are also expanding research with community-based programs, including efforts to build support for lethal means reduction.

Question 9. According to a 2018 Veterans Health Administration Survey of Enrollees, three million rural veterans solely rely on VA for their health care and are served by the Office of Rural Health Programs. These 3 million veterans represent a third of veteran enrollees who receive care in the VA. The FY21 request for the Office of Rural Health is $270 million, which is the same as the FY2020 request. Why have budget estimates for this office remained flat?

Response: The Office of Rural Health budget only addresses specific projects related to rural Veterans. In FY19, VA obligated more than $24 billion across the system to provide care to rural Veterans.

Question 10. Kansans are acutely aware of the challenges of care delivery in a rural setting. How will the Telehealth Clinical Resource Hubs work as a tool for VA to better extend care to rural veterans, and more specifically how will this important tool be fully integrated with the E-H-R-M?

Response: Clinical Resource Hubs (CRH) are VISN owned, VISN operated group of clinicians that provide clinical services to areas of greatest need across a VISN through Mobile Deployment Teams (MDT). MDT's are comprised of virtual and in-person deployable staff typically consisting of (Physicians, PA-C's, NP's, Clinical Pharmacists, Nurses, Psychologists, Psychiatrists, Counselors, Social Workers, and other staff as determined by the VISN). The VISN 15 CRH just started its program in FY20 and is currently building a CRH to support underserved and rural facilities in Kansas with a priority focus of expanding primary care and mental health services. Regarding the current Electronic Health Record Modernization (EHRM) in VHA: All VISN CRH staff are fully capable and wholly utilize the current EHRM system (CPRS) in VA to deliver servicers to Veterans. Regarding the new EHRM in VHA: VISN 20 is the location of the initial operating sites for Cerner in VA. The CRH in VISN 20 is currently engaged with developing workflows and full integration of the new medical record system. In order to maintain consistent and continuous care for the Veteran, each VISN CRH will receive training for the new EHRM as their respective VISNs go live.

Question 11. The Department announced the hiring of more than 16,000 new employees to respond to the COVID-19 pandemic since March 29th, including over 3,000 nurses and more than 500 doctors. VA has also noted a greatly reduced onboarding timeline for many of these providers as you worked with OPM to waive certain requirements to get these health care professionals in place as quickly as possible.

> *Question 11a.* How will these new hires impact VHA's plan for 14,000 new hires in the FY21 budget request?

Response: The new hires in FY20, including those during COVID-19, have contributed to a 2.5% net increase in the VHA workforce of 8,656 employees to date. This year's net increase will not impact plans for future hiring against the FY21 budget due to increased Veteran demand.

> *Question 11b.* Will the success in rapid hiring for these new employees lead to changes in hiring requirements on a permanent basis going forward? How can Congress help with needed hiring changes?

Response: Yes, VA needs additional resources and authorities to help bring on more employees and retain staff. Given current resources, it will be difficult to sustain accelerated hiring. VA is currently seeking support for a number of legislative changes, including removing restrictions on employment of Housekeeping Aids. Most recently, VA submitted

COVID-related and permanent proposals that would establish an exception to the hiring requirements under 5 U.S.C. § 3310 for Housekeeping Aids in VA. Excepting VA from this restriction will expedite recruitment and hiring processes for Housekeeping Aids, especially within VHA. In addition, statutory changes are needed to ensure that in the future, during times of a declared public health emergency, national emergency, or domestic emergency, flexibilities are available without further statutory change.

Since the flexibilities were put in place to respond to a specific emergency situation, most have specific time limits and are intended for use to exclusively support COVID-19-related operations. Some of the flexibilities may require statutory or regulatory relief. VA will propose and request changes for those flexibilities that are identified as having been the most beneficial in assisting with meeting patient care needs and are appropriate for continued use during normal and/or emergency operations.

VA's Office of the Chief Human Capital Officer is assembling a multidisciplinary team to assess the feasibility and appropriateness of the continued use of a number of these flexibilities and policy changes. Some of the flexibilities will require statutory or regulatory relief. Congress may be able to assist with approving any proposed relief that VA identifies as the most beneficial in assisting with meeting the needs of our Nation's Veterans, and that would be appropriate for continued use during normal and/or emergency operations.

Question 12. The current budget for the Homeless Veteran Program Office is more than $1.8 billion and $70 million over FY20 appropriations. The Department also received $300 million in supplemental funds to assist the program office with the response to the COVID-19 outbreak.

> *Question 12a.* The GAO recently conducted a study of VA homelessness programs and recommended the VA Under Secretary for Health clearly communicate with local VA staff and service providers performance measures and how to obtain and provide feedback on those performance measures. Has the Department developed a plan to carry out the GAO recommendations? If so, please provide the plan.

Response: The VHA Homeless Program Office (HPO) is aware of the Government Accountability Office (GAO) recommendation referenced above but has not yet formally received it with a request for action. As soon as we receive the formal recommendation, we will provide a response with our plan to carry out the GAO recommendations. In the meantime, we continue to provide regular input to VA staff and service providers regarding monthly performance on key measures. Technical specifications and targets are published and available to VA staff and service providers as well.

> *Question 12b.* 15% of case manager positions are vacant. What is the Department's plan to fill those positions?

Response: On July 17, 2020 the Assistant Under Secretary for Health for Operations released the Required Filled Rates for Homeless Program Specific Purpose Funded Positions memorandum to all Veterans VISNs and VAMCs to ensure there are adequate staffing levels to provide care to homeless Veterans. The memo sets the expectation that VAMCs have a minimum filled rate of 90% for all Homeless Program Specific Program-funded positions at any given time to meet the needs of Veterans served by VHA Homeless Programs. 90% is the standard target for filled rates, accounting for inevitable turnover in positions.

The memo requires removal of internal processes that slow down the hiring process at VAMCs; prohibits the appointment of temporary "Not-To-Exceed" positions; requires each VAMC under a 90% filled rate complete an action plan in partnership with local Human Resources, VAMC leadership, and the VISN Homeless Coordinator; and establishes a Homeless Program Office

implementation team to work intensively with VISN and VAMCs to support improved hiring rates.

Question 12c. How is the department maximizing the $300 million provided in CARES to assist homeless veterans through your programs?

Response:

Supportive Services for Veteran Families (SSVF) program:

On April 24, 2020, $201.5M in CARES Act funds was distributed to grantees. SSVF is focusing on three critical areas: emergency housing in hotels/motels; Housing and Urban Development – VA Supportive Housing (HUD-VASH) support while Public Housing Authorities (PHA) have limited functioning; and expanded prevention in response to high unemployment.

Between March 17, 2020 and June 26, 2020; 8,925 (with over 3500 in June 2020 alone) hotel/motel placements have been made to reduce risk of COVID-19 exposure for vulnerable Veterans. Through June of FY20, over 87,000 Veterans and family members have been served with 80% of exits placed in permanent housing.

Grant and Per Diem (GPD) program:

VA allocated $88 million in funding to the GPD program and waived per diem limits during the crisis to empower GPD grantees to provide all needed emergency housing and supportive services for Veterans who need to be isolated for their safety or the safety of others.

As of July 17, 2020, GPD has approved 420 per diem rate increase requests tied to 8,989 transitional housing beds and seven service centers. There has been $39,194,546 allocated to the field. An increased per diem in funding available facilitated physical distancing and provide safe housing for Veterans, including:

- Additional temporary space to support social distancing.
- Regular deep cleaning of facilitates.
- Personal protective equipment (PPE).
- Disposable phones or other equipment to facilitate remote Veteran access to care/services.
- Staffing to support services in alternate sites of care.

Health Care for Homeless Veterans (HCHV) Program:

VA allocated $10 million in CARES Act funding to provide emergency shelter and supportive services during the crisis through the HCHV Contract Residential Services (CRS) Program, including placement in hotel rooms for Veterans needing emergency placement or isolation to avoid spreading the virus. Housing will be paired with care, treatment, and rehabilitative services.

Unlike GPD, these contracts do not have a fixed cap on the daily rate, and the programs, services, and costs vary widely. Because of this funding flexibility, these programs are uniquely suited to provide emergency shelter and supportive services during the COVID-19 crisis,

including paying for hotel/motel rooms for Veterans needing emergency placement or isolation. As of July 17, 2020, $6,061,437.00 has been allocated to the field.

Approximately 80 percent of the funding allocated has been used to increase HCHV CRS resources either through an increase in the available beds at a CRS program or establishing new temporary HCHV CRS programs. Additionally, 20 percent of the approved funding was to establish a temporary per diem rate increase as approved by the contracting officer to enable existing HCHV CRS providers to purchase necessary PPE, establish enhanced cleaning protocols, allow providers to utilize hotel/motel rooms for at risk Veterans, especially those in large congregate living facilities.

HCHV will continue to support the requests for funding related to COVID-19 response contingent upon the duration of the pandemic and contingent upon VA's funding availability.

Question 13. In recent years the Department has seen funding for grants to adaptive sports partners nearly double. The number of veterans served by the VA's adaptive sporting programs, including women veterans, continues to grow directly and through community partners.

> *Question 13a.* Are rehabilitation events adequately resourced to adapt to any needed adjustments to best serve this changing group of veterans?

Response: Yes, the Office of National Veterans Sports Programs and Special Events (NVSPSE) is adequately resourced. The six national rehabilitation events (National Veterans Wheelchair Games, National Veterans Creative Arts Festival, National Veterans Golden Age Games, National Disabled Veterans Winter Sports Clinic, National Disabled Veterans TEE (Training, Exposure and Experience) Tournament and National Veterans Summer Sports Clinic) utilize appropriated funds along with strategic partnerships to support these programs. Veteran Service Organization (VSO) partners such as Disabled American Veterans (DAV), Paralyzed Veterans of America (PVA), American Legion Auxiliary, along with corporate and individual sponsors, partner with VA in their support to fund programming.

Growth has been realized in all programs over the past three years, and especially the National Veterans Golden Age Games designed for Veterans 55 and older has seen a rapidly trending interest. Expanding the capacity of this and other events will require concerted planning and programming to support the increase in the numbers of Veterans wanting to participate. VA has also made concerted efforts to increase the participation of women Veterans, who now comprise over 18 percent of the Veterans served by National Veterans Sports Programs and Special Events. For the National Veterans Creative Arts Festival, more than 24 percent of the 3,700 Veterans that entered local competitions at their VA medical facility were women in FY 2019.

Current efforts focus on aligning program costs to mission-critical tasks and eliminating non-essential activities, improving efficiencies in program planning and eliminating costs related to planning redundancies, expanding community sponsorships to defray operational expenses, and expansion of community volunteers to minimize demand for VA staffing resources.

> *Question 13b.* How will the Department make certain that veterans in underserved communities and veterans with complex physical disabilities are adequately served?

Response: VA national rehabilitation events are designed to serve Veterans with the most complex disabilities including spinal cord injury, limb amputation, traumatic brain injury, neurologic conditions (multiple sclerosis, stroke and amyotrophic lateral sclerosis), visual impairments and mental health conditions. The national rehabilitation events are inclusive of the newest technologies in adaptive sports and therapeutic arts to assure inclusion of Veterans with the most complex challenges.

A key strategy to meet the needs of the Veterans served is to matrix the expertise of community-based sports experts with VA clinical staff that serve Veterans daily (i.e., recreation therapists, physicians, physical therapists, blind rehabilitation specialists, creative arts therapists, occupational therapists, rehabilitation nurses, spinal cord injury care providers, prosthetists, orthotists and mental health providers). Additionally, the VA national program office supports continuing education sessions for adaptive sports and therapeutic arts providers, both virtually and face-to-face at the national rehabilitation events.

Additionally, the VA Adaptive Sports Grant (ASG) program offers grants to adaptive sports providers across the country to provide opportunities for disabled Veterans within their communities. Congress has increased funding for the VA Adaptive Sports Grant Program from eight million dollars to fifteen million dollars since FY 2018. A priority stated in the notice of funding availability for the FY 2020 VA ASG program was, "Providing adaptive sports activities for Veterans, and members of the Armed Forces, with disabilities in geographic regions where limited sports opportunities are available for this population."

Question 14. In response to the COVID-19 outbreak, Congress passed two laws designed to better facilitate education benefits to veterans.[1]

> *Question 14a.* Does the Department have any additional requests for authorization to facilitate veteran education and training in light of COVID-19?

Response: While Education Service does not currently have any additional requests, we are committed to working with Congress to identify and implement future legislative changes to help Veterans adjust to the new educational and training environment as a result of COVID-19.

VR&E has no additional requests currently.

> *Question 14b.* Does the department expect to have additional funding needs for IT related to the recent changes to the law? If so, explain the funding requirements.

Response: The Department of Veterans Affairs (VA) Office of Information and Technology (OIT) has requested $27 million in the President's FY21 Budget for IT systems to support VA EDU Services. OIT received $1.9 million in COVID-19 supplemental funds to initiate education IT modernization efforts related to the legislation referenced. OIT has identified a need and is seeking $14 million in additional funding for FY21, apart from or in addition to any amount requested by VA EDU, to cover costs related to the additional COVID-19 legislation.

Question 15. The Department's VET TEC program has already run out of funds and needs an additional $30 million through the end of this fiscal year to continue. How did the Department

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[1] *P.L. 116-128* and *P.L. 116-140*

run out of funds halfway through the fiscal year? Please provide the business model for the program.

Question 16. Over 125,000 Compensation and Pension (C&P) were put on pause in response to the COVID-19 outbreak.

Question 16a. How does the department plan to eliminate the backlog? What is the Department's timeline for eliminating the backlog?

Response: Based on the current backlog inventory of approximately 190,000 claims as of July 16, 2020, VBA is projecting that the backlog will continue to increase into fiscal year (FY) 21 without overtime. VBA has submitted an updated FY21 overtime funding request to assist in eliminating the backlog. With the assistance of overtime funding, VBA will work to return backlog inventory levels to pre-COVID levels as quickly as possible in FY21.

Question 16b. What wait time should a veteran expect for a decision?

Response: Currently, the average days pending (ADP) for a rating claim is 118 days. The ADP has risen by 37 days since the end of March. This increase is a direct result of delays with in-person medical disability examinations and obtaining federal records secondary to COVID-19. Of the exam inventory pending, 81% are located in areas where contract exam vendors are currently resuming in-person examinations.

Question 16c. As VBA reopens, what guidance has the Department provided to providers and contractors as to how to begin to examine veterans and in a way that is safe and comfortable for the veteran?

Response: VBA suspended in-person C&P examinations until May 28, 2020, when it partially resumed these examinations subject to vendors and their providers meeting CDC, state, and local sanitation, screening, personal protective equipment, and distancing requirements. VBA did not authorize any such examination until the vendor submitted and received VBA approval of an implementation plan regarding these requirements. VBA issued the following guidance to the vendors:

Question 16d. Does the Department expect to need funds above the FY21 budget estimate to address the backlog in claims as a result of the COVID-19 pause?

Response: Yes. VBA projects that an additional $85.3M will be required in FY21 for overtime to clear the COVID-related backlog. Based on the current backlog inventory of approximately 190,000 claims as of July 16, 2020, VBA is projecting that the backlog will continue to increase into FY21 without overtime. VBA has submitted an updated FY21 overtime funding request to assist in eliminating the backlog. With the assistance of overtime funding, VBA will work to return backlog inventory levels to pre-COVID levels as quickly as possible in FY21.

Question 16e. Can the Department utilize funds for overtime for claims examiners? If so, how long will these funds last?

Response: Yes. VBA can utilize additional funds for claims examiner overtime. VBA projects these funds will be sufficient for the entirety of FY21. The overtime requested will be utilized for claims examiners. VBA has submitted an updated FY21 overtime funding request to assist in eliminating the backlog. With the assistance of overtime funding, VBA will work to return backlog inventory levels to pre-COVID levels as quickly as possible in FY21.

Question 17. In response to the COVID-19 outbreak, the CARES Act grants forbearance for homeowners with VA-guaranteed loans. Does the Department have the necessary funding/FTE's to assist with increased demand for loan servicing and loss mitigation in order to avoid foreclosure?

Response: Loan Guaranty (LGY) has adequate resources to serve VA Home Loan borrowers. VA is not requesting additional full-time equivalents (FTE) at this time to specifically address forbearance assistance under the CARES Act. VA does not pay for the servicing of VA-guaranteed loans. Servicers must meet regulatory requirements for the servicing of VA-guaranteed loans, in addition to Consumer Financial Protection Bureau (CFPB) and other federal requirements.

Mortgage Servicers provide the primary servicing of VA-guaranteed loans, while VA Loan Technicians provide supplemental assistance to VA borrowers. VA Loan Technicians provide oversight of each delinquent loan to ensure Veterans are receiving every opportunity to retain homeownership. VA Loan Technicians are individually assigned loans once they reach 61 days delinquent, so Veterans have a single point of contact while resolution of the delinquency is in process. As part of their duties, VA Loan Technicians are prepared to answer questions, provide guidance, and act as the Veterans advocate with the Servicer.

Question 18. How many homeowners with VA-guaranteed loans have requested forbearance under the CARES Act?

Response: As of June 30, 2020, nearly 111,000 Veteran homeowners with VA-guaranteed loans have requested forbearance under the CARES Act as reported by Servicers.

Question 19. The Department relies on servicers to pursue loss mitigation with oversight from the Department, of which the VALERI reporting system is a critical component. The VA began implementation of the newer, in-house VALERI-R system in 2019.

Question 19a. What developments or enhancements are needed to improve VALERI-R and the Departments oversight of servicers participating in the VA Loan Guaranty Service?

Response: VA successfully deployed the VALERI-R system in May 2019. Prior to May 2019, VA relied on a managed-service contract for the previous version of VALERI. Since VA owns the source code for VALERI-R, the department can rapidly make changes to improve oversight. For the example, in June 2020, VA deployed a VALERI-R system change to specifically track and monitor the number of Veterans who requested forbearance under the CARES Act. Additionally, VA is implementing performance dashboards to evaluate servicer performance.

Question 19b. How will VALERI-R's improved capabilities better protect veteran homeowners from foreclosure?

Response: VA will have access to normalized data and visualizations, which will result in prompt and better-informed decisions to assist all Veterans with a VA mortgage. For example, VA will be able to conduct targeted risk-based oversight to ensure Veteran homeowners are protected from foreclosure. The servicer performance dashboard will enable VA to trend and rank servicer performance to address deficiencies, which will also help to improve Veteran outcomes regarding foreclosure prevention.

Question 20. Funding for Toxic Exposure initiatives is spread across numerous program offices. According to your budget submission, there is increased interest in creating self-reported registries despite known limitations. VA and DoD are still working on the Individual Longitudinal Exposure Record (ILER) which will replace registries with a record for each servicemember with location, time/date and exposure monitoring noted. In the beginning of May, you announced that More than 204,000 veterans and service members have signed on to the Department of Veterans Affairs Airborne Hazards and Open Burn Pit Registry. To participate in the registry, servicemembers and veterans must complete the questionnaire and receive an in-person exam. Because of the COVID-19 pandemic, most VA facilities are deferring those exams. As the VA and DoD continue to work toward full operational capability of the Individual Longitudinal Exposure Record (ILER) system, adequate resourcing of the current efforts underway will be essential toward achieving a system where every veteran can have faith that every aspect of their service-related health needs will be addressed.

Question 20a. How will you balance decreasing the backlog for exams initiated by signing up for the Burn Pit Registry with insuring ILER receives adequate funding?

Response: The Airborne Hazards and Open Burn Pit Registry (AHOBPR) exams and ILER funding are two separate actions. DoD and the VA work closely on both projects.

Facilities with the most success with both implementing ILER and completing AHOBPR exams are those designated as dedicated Environmental Health Clinics (EHC). When EH services are embedded in compensation and pension (C&P) or primary care clinics competing priorities often put EH services in a subordinate role. With additional funding VA could do a pilot proof of concept for the EHC model. VA could implement one EHC per VISN with $9,000,000 in funding; ($500,000 for at least 18 clinics). When ILER becomes part of the electronic health record, the legacy registries will fall under ILER. The legacy registries include: Ionizing Radiation, Agent Orange, Gulf War, Toxic Embedded Fragments, Depleted Uranium and Airborne Hazards and Open Burn Pits.

VA through the Post Deployment Health Services (PDHS) and medical centers and VISNs are diligently working to reduce the backlog of exams. The AHOBP Registry offers an optional follow-on clinical exam after completing the Part 1 online questionnaire, about 50% of Veterans indicate that they would like an exam.

As of July 15, 2020, there were 209,986 participants in the AHOBP Registry of which ~90,632 would like an exam (see calculation below*); 14,000 had Gulf War Registry exams which overlaps the AHOBPR exam and an additional 14,152 Veterans had the AHOBP registry exam.

Therefore, ~28,000 in the AHOBPR received a registry exam. This number is likely an undercount, since early in the registry's existence, Veterans may have had an AHOBP exam that was not recorded on the burn pit template; the template auto-feeds into the registry. Widespread use of the AHOBP exam template did not occur until 2018.

*Denominator for Veterans (and Guard and Reserve) wanting an AHOBPR exam

209,986 - 28,722 active duty = 181,264 - 28,000 completed exams = 153,264

50 percent indicate that they would want an exam: 153,64 ÷ 2 = 76,632

In November 2019, PDHS reviewed AHOBP Registry participants and found that 97 percent were enrolled in VA health care and 74 percent were seen at VA in the previous two years. Therefore, the majority of the AHOBPR cohort receive health care at a VA facility. Active Duty obtain exams at a military treatment facility.

VA documentation of AHOBPR exams with training for EH clinicians at the EH Clinical and Coordinator Conference in 2018 and 2019. There are also continuing webinars, quarterly phone conferences and email updates to VA staff to increase AHOBP exams. Metrics on site productivity has also been shared with VAMC and VISN leaders. The current monthly average is 556. An increase in exams occurred in June 2020 as some sites reopened following COVID related closures. Several sites model best practices (El Paso, Orlando, Eastern Colorado) as dedicated EH clinics for all exposures and have increased their exams.

For Veteran safety and health some VA facilities deferred AHOBP Registry exams during COVID. In some areas, exams were done via telemedicine with arrangements for in-person exams as needed. Veterans have given positive feedback regarding tele-medicine exams.

Veterans who initially indicated they do not want an exam can change their mind at any time. Veterans who want to make an AHOBPR make an appointment with the local EH coordinator. The EH coordinator list is found at: https://www.publichealth.va.gov/exposures/coordinators.asp

DoD and VA are coordinating to ensure that all Service Members will receive an exposure assessment at various touch points in their military career. These are periodic health assessments, Post Deployment Health Assessments and the updated Separation History and Physical Examination (SHPE). When the new SHPE is fully implemented (Summer 2022), all Service Members leaving service will have an exam to address exposure concerns.

> *Question 20b.* What is the way-ahead for ILER and how are current toxic exposure research initiatives being prioritized?

Response: Provider access to and use of ILER is increasing. The initial goal is to ensure that at least one EH clinical team at each VAMC has an ILER account. In May 2020, 30 facilities (20 percent) had a user. ILER training is taking place now. One way to ensure ILER success and improving EH services is by professionalizing environmental health**. Currently, many of the ILER users and clinics performing AHOBPR are part time and housed within primary care or C&P clinics.

**Sites performing the most AHOBPR exams and with ILER accounts are those that have a dedicated mission to address ALL military EH issues. (A funding proposal was presented in section 1 paragraph 2.)

Toxic exposure research initiatives and priorities are set using many avenues. PDHS works with VSOs, DoD, EPA, news/media services, academia and Congress to identify and address concerns. The PDHS Epidemiology Service conducts surveillance and analyzes Veteran cohorts to prioritize newly emerging issues or follow longer standing environmental exposure concerns. Findings from these research studies help health professionals and policymakers, including VA and Congress, improve health care practices and policies for Veterans.

Question 21. The Department estimates that it would require total resources of approximately $62-$76 billion for capital infrastructure and activation costs to remediate all infrastructure gaps. Alarmingly, this includes $7 billion of pending seismic projects nationally. However, the budget request includes a total of only $1.9 billion for all construction projects. Without investing in these infrastructure gaps, how does the VA manage risk?

Response: VA's limited infrastructure investment funding for a large amount of construction requirements results in informed tradeoffs when addressing critical priorities and delays to closing infrastructure gaps. Since 2012, VA has used the annual Strategic Capital Investment Planning (SCIP) process to identify facilities infrastructure gaps and associated risks and prioritize investments to maximize effectiveness of available funds for competing priorities.

VA also utilizes other authorities to address both absence of additional funding and real property portfolio management. For example, energy performance contracting allows VA to make energy and water infrastructure improvements using little to no appropriated funds. These projects provide a vehicle to improve infrastructure outside the Non- Recurring Maintenance program while achieving savings through improved energy and water efficiency. The payments for these improvements are based on those savings and are made from current year operating funds through the course of multi-year contracts.

In addition, enhanced use lease authority allows out-leasing of underutilized assets for the purpose of developing supportive housing for homeless and at-risk Veterans and their families (a major VA priority). Projects executed under this authority remove the costs to VA for maintaining these underutilized properties.

Question 22. The Department is in the early stages of an extraordinary number of technology modernization projects right now. A few, like the Electronic Health Record Modernization (EHRM), have dedicated funding and oversight. Others have cobbled together funding and lack much of a paper trail.

> *Question 22a.* For EHRM does the FY21 budget estimate include all infrastructure and IT costs? If not, what are those estimates?

Response: As outlined in the Office of Electronic Health Record Modernization (OEHRM) and Department of Veterans Affairs (VA) Office of Information and Technology's (OIT) Electronic Health Record Modernization Integrated Infrastructure Plan, the offices closely collaborate to ensure infrastructure readiness and information technology (IT) requirements are met to support the optimal use of VA's new electronic health record (EHR) solution. OEHRM coordinated with OIT and the Veterans Health Administration (VHA) to identify the modernization upgrades required to support VA's new EHR solution beyond VA's traditional infrastructure and IT needs. The offices meet weekly to discuss planning and execution to promote efficiency, eliminate duplicated work, and leverage VA's economies of scale.

OIT funds the traditional VA infrastructure and IT refresh/upgrades required to maintain the department's existing systems. For example, IT Operations and Services End User Operations supports replacement and Windows 10 imaging. Similarly, the VHA Office of Healthcare Environment Facilities Programs funds facilities infrastructure (e.g., category 6A cabling, patch panels, fiber optics, power, cooling and uninterruptable power supply) which supports IT infrastructure, as it is part of VA's capital improvements, and managed through VA's Strategic Capital Investment Planning process. OEHRM funds the IT modernization upgrades required for VA's new EHR solution beyond VA's traditional infrastructure and IT needs including new devices such as desktops.

> *Question 22b.* Provide a detailed plan for what it would take to adequately resource the Department's IT needs and how that level of funding would be stewarded.

Response: OIT is identifying and justifying the level of IT funding required for current sustainment requirements, to keep up with VA Administration (VHA, VBA, NCA, etc.) growth, invest in IT modernization, and increase our current manpower level required to support our customers. OIT is currently working with VA leadership to submit a phase approached to fully fund VA IT.

> *Question 22c.* The Department's IT budget is one of the lowest in the Federal Government at 4.5% of the total agency spend. What steps is the Department taking to address these funding deficiencies, and how is it managing the risk?

Response: VA OIT has worked with the Office of Management and Budget (OMB) and Congress to identify the required funds to address cumulative and annualized VA technical debt and incorporate those needs into our Multi-Year Planning (MYP) requirements.

OIT created an Unfunded Requirements (UFR) Prioritization Management System, UFRPMS, which allowed OIT to identify and prioritize critical UFRs. Using the newly established Chief Executing Officer (CXO) Council and OIT Account Management Office (AMO), VA was able to review all of OIT's IT investments by prioritization to fund each investment based on most critical strategic need to minimize risk. OIT will continue working with the CXO Council and each VA Administration to assist in identifying and submitting a more comprehensive FY2022 budget request.

Ranking Member Tester

COVID-19's Impact on the FY21 Budget Request

Question 1. What is VA's projection for the number of veterans who will enroll in VA health care because of the pandemic?

Response: Currently, VA is observing a lag in new enrollment as stay-at-home orders remain in place and as Veterans defer care and do not access VA facilities, which is the primary access point for enrollment. In the longer term, based on analyses and experience from the 2008 recession, VA expects new enrollment to increase as a result of the COVID-related economic recession as Veterans lose employment-based health insurance. The current recession, however, is anticipated to impact VA differently from the 2008 recession. For example, the path of the recession is sharper and could rebound more sharply.

VA is continuing to closely monitor and analyze the economic conditions that potentially impact VA enrollment. Given the dynamic nature of the pandemic and the economy, we are unable to provide projected new enrollment as a result of COVID at this stage.

Question 2. What reliance rate for VA health care is this budget based on? Discuss how the reliance rate might change as a result of COVID-19.

Response: The FY21-22 budget was informed by the 2019 VA Enrollee Health Care Projection Model. That model estimated an overall reliance rate of 38 percent in 2020. This reflects the amount of health care that enrollees are expected to receive through VA as a percent of their total health care needs. Reliance rates vary significantly by health service categories and by enrollee demographics.

VA expects that reliance on VA health care will increase as a result of COVID, as enrollees choose to receive more of their care through VA (either in VA facilities or through community care) as a result of job losses. There are multiple factors that could influence the increase in reliance on VA, however. The Affordable Care Act has provided a stronger health care safety net and the recent CARES Act expanded access to the Consolidated Omnibus Budget Reconciliation Act (COBRA), which could dampen reliance increases. VA's expansion of access to community care through MISSION may increase reliance.

As the COVID-19 pandemic continues, VA is closely monitoring enrollee behavior, VA system changes, and the broader health care system to understand how changes are potentially impacting reliance.

Question 3. According to VA data, of the $20 billion authorized in the CARES Act, less than $3 billion has been obligated. Is VA having problems executing the remaining funds?

Response: No, VA is not having difficulty executing the funds. VA continues to spend CARES funding in line with patient and system needs as we prepare for future waves of the pandemic.

Question 4. Does VA have what it needs to meet all anticipated COVID-19 requirements?

Response: VA has sufficient funding to meet all anticipated COVID-19 requirements but seeks some additional flexibilities to ensure funds available for requirements that were not known at the time of the CARES Act supplemental funding.

Question 5. How will the FY21 budget request be affected with COVID-19-related closures of VA facilities, changes in how VA provides care, varying access to community care, etc.?

Response: The CARES Act provided significant resources to support VA's response to the COVID-19 pandemic. Between the CARES Act and our FY 2021 President's Budget request, VA has sufficient resources to pay for the increased grant and per diem rate. VA will continue to monitor and notify Congress should estimates change.

Homelessness

Question 6. The CARES Act provided $300 million for homeless programs – aimed at helping not just currently homeless veterans but also newly homeless or at-risk-of-becoming homeless veterans and their families. How is this supplemental funding being used to help keep veterans and their families from falling into homelessness? How have the additional appropriations been spent thus far? Do you expect to need additional funding to pay for the increased GPD rate?

Response: The CARES Act provided significant resources to support VA's response to the COVID-19 pandemic. Between the CARES Act and our FY 2021 President's Budget request, VA has sufficient resources to pay for the increased grant and per diem rate. VA will continue to monitor and notify Congress should estimates change.

Supportive Services for Veteran Families (SSVF) program:
On April 24, 2020, $201.5M in CARES Act funds was distributed to grantees. SSVF is focusing on three critical areas: emergency housing in hotels/motels; Housing and Urban Development – VA Supportive Housing (HUD-VASH) support while Public Housing Authorities (PHA) have limited functioning; and expanded prevention in response to high unemployment.

Between March 17, 2020 and June 26, 2020; 8,925 (with over 3500 in June 2020 alone) hotel/motel placements have been made to reduce risk of COVID-19 exposure for vulnerable Veterans. Through June FY 2020, over 87,000 Veterans and family members have been served with 80% of exits placed in permanent housing.

Grant and Per Diem (GPD) program:

VA allocated $88 million in funding to the GPD program and waived per diem limits during the crisis to empower GPD grantees to provide all needed emergency housing and supportive services for Veterans who need to be isolated for their safety or the safety of others.

As of July 17, 2020, GPD has approved 420 per diem rate increase requests tied to 8,989 transitional housing beds and seven service centers. There has been $39,194,546 allocated to the field. An increased per diem in funding available facilitated physical distancing and provide safe housing for Veterans, including:

- Additional temporary space to support social distancing.
- Regular deep cleaning of facilitates.
- Personal protective equipment (PPE).
- Disposable phones or other equipment to facilitate remote Veteran access to care/services.
- Staffing to support services in alternate sites of care.

Health Care for Homeless Veterans (HCHV) Program:
VA allocated $10 million in CARES Act funding to provide emergency shelter and supportive services during the crisis through the HCHV Contract Residential Services (CRS) Program, including placement in hotel rooms for Veterans needing emergency placement or isolation to avoid spreading the virus. Housing will be paired with care, treatment, and rehabilitative services.

Unlike GPD, these contracts do not have a fixed cap on the daily rate, and the programs, services, and costs vary widely. Because of this funding flexibility, these programs are uniquely suited to provide emergency shelter and supportive services during the COVID-19 crisis, including paying for hotel/motel rooms for Veterans needing emergency placement or isolation. As of July 17, 2020, $6,061,437.00 has been allocated to the field.

Approximately 80 percent of the funding allocated has been used to increase HCHV CRS resources either through an increase in the available beds at a CRS program or establishing new temporary HCHV CRS programs. Additionally, 20 percent of the approved funding was to establish a temporary per diem rate increase as approved by the contracting officer to enable existing HCHV CRS providers to purchase necessary PPE, establish enhanced cleaning protocols, allow providers to utilize hotel/motel rooms for at risk Veterans, especially those in large congregate living facilities.
HCHV will continue to support the requests for funding related to COVID-19 response contingent upon the duration of the pandemic and contingent upon VA's funding availability.

Question 7. Describe how VA is preparing to assist at-risk-of-becoming homeless veterans and their families as eviction moratoriums are beginning to be lifted across the country?

Response: On April 24, 2020, VA allocated $202 million to the SSVF program to provide emergency housing, including in hotels, and homelessness prevention assistance to mitigate the expected wave of evictions and potential homelessness that will result from extensive unemployment. Funds for this program will also assist the HUD-VASH program in placing Veterans in safe housing to isolate them from the virus while they await their housing voucher.

On July 16, 2020, VA announced that an additional $400 million in CARES funding will be made available to SSVF grantees to extend support for the COVID-19 response through FY 2021. SSVF has provided extensive technical assistance to grantees and provided regulatory relief through the Stafford Act, giving SSVF providers significant new capabilities to address the wave of evictions anticipated as a result of unemployment caused by the COVID-19 public health emergency.

Question 8. How would VA rate its ability to care for homeless veterans who may have been exposed to or tested positive for COVID-19, especially those residing in communal living situations?

Response: The VHA HPO took early action to care for homeless Veterans through the March 11, 2020 release of the 10N memo entitled "Homeless Program Office (HPO) Coronavirus Disease 2019 (COVID-19) Response Suggestions" to proactively plan and adopt careful infection prevention methods, including social distancing practices in congregate settings, all guided by CDC recommendations. HPO also developed Options for Social Isolation Under the COVID-19 National Emergency: Guidance for GPD, HCHV CRS, and SSVF to provide official guidance regarding the use of existing program authorities to support social distancing practices and quarantine/isolation efforts particularly for vulnerable Veterans at an increased risk of infection and negative outcomes based on CDC criteria. Further, the GPD Program disseminated guidance to grantees for COVID-19 positive and presumptive positive Veterans temporarily placed in hotels and motels in the document GPD Grantee Guidance: Wellness and Symptom Checks for COVID-19 Positive and Presumptive Positive Veterans in Hotels and Motels with the expectation that the grantee will develop a plan to ensure Veterans' medical, mental health, and social needs are met during isolation. In addition, the recent 10N memo entitled "Protocol for Homeless Veterans At-Risk of COVID-19 Placed in Hotels and Motels by Supportive Services for Veteran Families Program" addresses the need for Veterans placed in hotels/motels and co-enrolled in SSVF and HUD-VASH to gain prompt access to VHA health care services through primary care.

Question 9. Can VA commit to testing every homeless veteran and getting them to the appropriate care, as you have done with veterans living in nursing homes?

Response: The VHA HPO supports proactive testing of Veterans residing in congregate settings for early identification of COVID-19 cases and to aid in mitigating disease outbreaks in these high-risk locations. HPO has developed a policy memo and standard operating procedure (SOP) document for universal testing in all GPD and HCHV CRS programs that are currently under review by VHA leadership. The testing memo and SOP provides the requirement that VAMC identify a COVID-19 testing team to conduct testing prior to program admission and on an ongoing basis for Veterans currently enrolled in GPD and HCHV CRS who are eligible for VHA care.

The COVID-19 testing team must consist of at minimum one VHA provider for ordering of the test and provision of follow-up care. Additional recommendations in the proposed memo and SOP include the following: 1) coordinate testing events on site using the COVID-19 testing teams, rather than transporting Veterans to local VAMCs, to reduce the chance of disease

transmission and increase access, 2) conduct testing events on weekends rather than weekdays to enhance access to testing for Veterans who may lack transportation or work primarily during the weekdays, and 3) include staff from Homeless Patient Aligned Care Teams (H-PACT) for COVID-19 testing teams when possible

In addition, on July 16, 2020, the Assistant Under Secretary for Health for Operations released the Protocol for Homeless Veterans At-Risk of COVID-19 Placed in Hotels and Motels by the SSVF Program memorandum to all VISNs and VAMCs, requiring prompt access to VHA health care services for Veterans placed in hotels and motels by the SSVF program. The memo also describes a new health care navigator position that will be recruited by SSVF grantees. These navigators will work with VA health care staff and other community-based health care providers to ensure that vulnerable homeless Veterans are quickly linked to appropriate care and this care is coordinated with other services designed to lead to permanent housing placement.

Compensation and Pension Exams

Question 10. Will VA's current $3.207 billion FY21 budget request be adequate to fund the increased compensation and pension examination appointments for Veterans with the substantial backlog that has occurred due to COVID-19 pandemic?

Response: Yes, VBA's FY21 budget request is adequate to cover the excess inventory of C&P examination requests created as a result of the COVID-19 pandemic, as well as any increased volume of requests that VBA may receive post-pandemic.

VBA's request for $3.207 billion in FY21 does not include funding for contract exams. VBA's mandatory compensation and pension (C&P) account is authorized to reimburse VBA's General Operating Expenses (GOE) account for contract exams. In the 2021 President's Budget, VBA estimated contract exams would cost $2.233 billion in FY21. Although this estimate will likely increase due to COVID-19, VBA does not currently plan to request additional C&P funding from Congress for FY21.

Based on the current backlog inventory of approximately 190,000 claims as of July 16, 2020, VBA is projecting that the backlog will continue to increase into FY21 without overtime. VBA has submitted an updated FY21 overtime funding request to assist in eliminating the backlog. With the assistance of overtime funding, VBA will work to return backlog inventory levels to pre-COVID levels as quickly as possible in FY21.

Telehealth

Question 11. Is VA's current $1.3 billion FY21 request sufficient to fund the increase in telehealth appointments that has occurred due to the pandemic?

Response: VHA's FY21 telehealth budget request is sufficient based on current plans with one potential exception. The equipment needed to support Veterans access to technology and internet services, such as iPads, iPhones and related equipment items, will exceed initial projections if the COVID-19 Pandemic emergency continues.

Question 12. What concrete steps is VA taking to extend telehealth access to rural veterans or veterans who are experiencing homelessness?

Response: VA program offices continue to work together and in collaboration with VAMCs and VISNs to identify barriers related to provision of telehealth services to homeless Veterans. VA identified that a key barrier related to provision of telehealth services to this population is the lack of access to telehealth technology for both VA homeless program staff and Veterans. As VA homeless programs rapidly mobilize resources and strategies to move Veterans into independent, permanent housing and hotels/motels to promote physical distancing, technology is vital to prevent these vulnerable Veterans from becoming socially isolated, which may trigger or exacerbate mental health symptoms. Technology also provides a mechanism to ensure that Veterans remain engaged with homeless program providers to monitor safety and wellbeing, participate in preventative healthcare, attend virtual groups and recovery programs, and conduct virtual housing and job searches.

Recognizing the need for these technologies, VA is increasing capacity in its homeless programs by expanding telehealth and telecommunications capabilities. The CARES Act specifically requires VA to ensure that telehealth capabilities are available during a public health emergency for case managers of, and homeless Veterans participating in, HUD-VASH. In response to this requirement, the VA's Office of Connected Care (OCC) developed a process to ensure that HUD-VASH case management team members have the equipment necessary to provide telehealth services. An initial assessment of provider equipment needs resulted in procurement of approximately 600 iPads and more than 20,00 additional pieces of telehealth technology equipment (webcams, speakers, monitors, and headsets) which are currently in the process of distribution to the field. Additionally, OCC has expanded their equipment loaner program to include iPhones for HUD-VASH Veterans. They have procured these devices and are developing a process for dissemination to the field.

Additionally, at the end of April 2020, VA obtained authority to purchase smartphones and data plans using appropriated funds for Veterans, and in June 2020, received $17M in CARES Act funding to purchase approximately 50,000 disposable smartphones with unlimited data plans for Veterans in VA homeless programs to ensure that Veterans remain connected with caregivers and supports, participate in telehealth, and have access to employment and housing resources. VA is currently expediting procurement and dissemination of the phones to VAMC homeless program leads for distribution to Veterans engaged in homeless programs. The next steps are pending solicitation of a contract and Office of General Council (OGC) approval, due to the dollar amount. VA also received a 600,000 Amazon donation prior to the CARES Act funding approval and worked with the Office of Procurement, Logistics, and Acquisition (OPLA) to sole source a contract and disseminate 1,200 phones to homeless program leads at VAMCs in following cities: Boston, Philly, Battle Creek, Palo Alto, Las Vegas, and Kansas City. These

phones arrived on or around July 22, 2020 and were immediately disseminated to Veterans in need by local homeless program leads.

VA's Accessing Telehealth through Local Area Stations (ATLAS) initiative is also addressing the barrier in rural and remote areas where fewer options for connectivity are available. At five Walmart locations and several VSOs, private rooms with telehealth equipment and high-speed internet have been established for Veterans to securely connect to their VA care teams by telehealth. While the ATLAS project was initially paused to ensure safety during the pandemic, the initial locations are beginning to open with new infectious disease procedures and hopes for expansion.

VA is currently partnering with Microsoft to help expand internet access to select rural communities through their "Airband initiative." The Airband initiative leverages TV white space for broadband connectivity and supports digital skills training where it provides service. VA is accelerating the implementation of a national digital divide consult. This consult will be used when Veterans could benefit from connected care technologies but are identified as lacking access to the technology or internet connection necessary to participate. Through this consult, VA intends to help Veterans leverage benefits available through VA, other federal agencies, and the private sector to help Veterans connect remotely with VA services. The VA initiatives that will be initially available through the digital divide consult include the connected iPad program and a new connected phone pilot program for HUD-VASH Veterans. Through the consult, Veterans will also be assessed for eligibility for the Federal Communications Commission's (FCC) LifeLine program which can subsidize a Veterans internet or phone service.

VA is also seeking additional private sector partners to help support Veteran access to internet services. A request for information (RFI) was recently released to garner input and ideas. VA has previously established successful partnerships with several private sector companies for this purpose including with Microsoft, Verizon, T-Mobile, SafeLink by Tracfone, and Sprint (now owned by T-Mobile) and will be announcing additional partnerships soon. Through the RFI, VA intends to find additional partners ready to support Veteran's access to telehealth services.

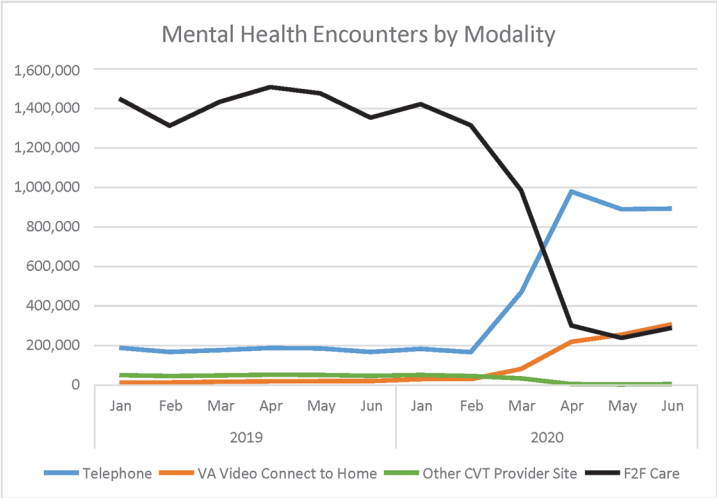
Mental Health

Question 13. Is VA projecting an increase in mental health appointments, whether that is in-person or through telehealth, because of the coronavirus? Can you provide a month-by-month breakdown from January 2020 to present of how many mental health appointments have taken place, disaggregated by modality (in-person, telephone, video connect, etc.)? Moreover, provide corresponding figures from 2019 to compare.

Response: The Mental Health Outpatient chart below shows the trends for the disaggregated modalities:

Year	Month	Telephone	VA Video Connect to Home	Other CVT Provider Site	F2F Care
2019	Jan	188,066	13,452	50,167	1,448,862
	Feb	167,486	13,773	44,895	1,312,892
	Mar	176,730	16,343	48,744	1,434,459

	Apr	186,881	18,866	52,062	1,508,476
	May	185,184	20,313	50,694	1,476,652
	Jun	167,585	19,847	46,251	1,353,469
2020	Jan	182,481	29,968	50,908	1,422,084
	Feb	166,521	29,639	45,476	1,314,918
	Mar	468,203	81,626	33,494	985,754
	Apr	979,131	218,653	4,237	301,871
	May	889,465	255,828	3,027	238,877
	Jun	893,293	307,712	4,984	290,015



VHA is anticipating the continued increase of Veterans seeking mental health care. The COVID-19 pandemic has resulted in a significant disruption of normal society patterns, including increased unemployment and job loss, altered healthcare seeking behaviors, and increased alcohol sales, which are commonly associated with increased mental health distress.

As requested, below are the completed appointments for mental health for FY19 and FY20 separated out by modality.

Modality	All	Face-to-Face	Other Telehealth	Telephone	VA Video Connect

OCT-FY19	1,798,370	1,504,898	98,525	184,666	10,281
NOV-FY19	1,584,159	1,319,310	87,615	167,179	10,055
DEC-FY19	1,471,272	1,223,862	82,118	155,541	9,751
JAN-FY19	1,750,561	1,448,862	100,181	188,066	13,452
FEB-FY19	1,583,822	1,312,892	89,671	167,486	13,773
MAR-FY19	1,724,871	1,434,459	97,339	176,730	16,343
APR-FY19	1,818,005	1,508,476	103,782	186,881	18,866
MAY-FY19	1,783,259	1,476,652	101,110	185,184	20,313
JUN-FY19	1,633,212	1,353,469	92,311	167,585	19,847
JUL-FY19	1,746,798	1,444,807	97,230	182,150	22,611
AUG-FY19	1,761,447	1,454,432	99,210	183,271	24,534
SEP-FY19	1,644,899	1,359,584	92,883	168,602	23,830

Modality	All	Face-to-Face	Other Telehealth	Telephone	VA Video Connect
OCT-FY20	1,808,258	1,495,458	103,147	182,625	27,028
NOV-FY20	1,521,032	1,251,554	87,047	158,164	24,267

DEC-FY20	1,527,526	1,250,655	88,534	163,041	25,296
JAN-FY20	1,736,252	1,422,038	101,770	182,478	29,966
FEB-FY20	1,602,022	1,314,891	91,007	166,487	29,637
MAR-FY20	1,601,947	985,900	66,366	468,053	81,628
APR-FY20	1,507,111	301,997	7,483	979,015	218,616
MAY-FY20	1,389,736	239,304	5,328	889,334	255,770
JUN-FY20	1,499,855	290,727	9,069	892,534	307,525

Question 14. Will VA need funding above what is in the FY21 budget request to provide these mental health appointments, whether that is in person or through telehealth?

Response: The CARES Act provided significant resources to support VA's response to the COVID-19 pandemic. Between the CARES Act and our 2021 President's Budget request, VA should have resources to meet the need. VA will continue to monitor and notify Congress should estimates change.

The FY21 telehealth budget request is sufficient to support telemental health plans with one potential exception. The equipment needed to support Veterans access to technology and internet services, such as iPads, iPhones and related equipment items, will exceed initial projections if the COVID-19 Pandemic emergency continues.

Question 15. How is VA tracking veteran suicide through this pandemic?

Response: VA is tracking Veteran suicide and suicide-related behavior through the COVID-19 pandemic through ongoing assessment of available data sources. Definitive information regarding pandemic-related suicide mortality requires comprehensive assessment of Veteran suicide mortality. The CDC National Death Index (NDI) is the gold standard of US mortality datasets. It is based on death certificate records compiled each year by CDC, working with each State's Vital Statistics office. NDI data provide cause-specific mortality data and when 2020 data become available (anticipated in 2022), these will provide important information. In the meantime, VA's monitoring has relied on more immediate indicators of suicide-related behavior. These include assessment of suicide attempts and suicide deaths as documented from Veterans Health Administration (VHA) facilities. For example, facility Suicide Prevention Coordinators

document suicide deaths and non-fatal suicide attempts through the Suicide Behavior and Overdose Report (SBOR) and Suicide Prevention Applications Network (SPAN) systems, the Comprehensive Suicide Risk Evaluation assessments, and through suicide attempt diagnosis coding. From these sources, VA tracks documentation of suicide-related behavior. Other tracking includes Emergency Department and Urgent Care encounters related to suicide attempts, and suicide risk screen assessment and documentation of suicidal ideation. Additional surveillance includes tracking of all-cause mortality for Veterans receiving care through the Veterans Health Administration. Analyses consider week-by-week trends in all-cause mortality, overall and for patients with versus without mental health diagnoses. Although not specific to suicide mortality, trends provide an overall assessment of pandemic-related factors on mortality for Veteran VHA users.

Caregivers

Question 16. Explain how the FY21 Budget Request supports expansion of eligibility to veterans of all eras.

Response: The 2021 President's Budget request is consistent with AQ48 - Proposed Rule - Program of Comprehensive Assistance for Family Caregivers Improvements and Amendments under the VA MISSION Act of 2018 published to the Federal Register on March 6, 2020 for public comment and was utilized to determine the FY 2021 submission.

Question 17. On what date does VA anticipate allowing applications for the new Program?

Response: VA will begin accepting applications for Program of Comprehensive Assistance for Family Caregivers from Veterans of other eras in phases. The first phase of program expansion will occur once the Secretary has certified that VA's new caregiver IT system is fully implemented and final regulations have been published. The Caregiver Record Management Application is on track for SECVA certification in late summer/early fall 2020. VA's Office of Information Technology is holding weekly Program Management Reviews with the appropriate stakeholders to closely monitor progress.

Research

Question 18. What guidance has gone to VA doctors about the use of hydroxychloroquine given additional studies have been released?

Response: Since the beginning of the COVID-19 pandemic, Pharmacy Benefits Management Services (PBM) has released several guidance documents to the field related to hydroxychloroquine use focusing both on safety and the available evidence base for use in COVID-19. PBM reviews the published literature daily, and maintains a living document outlining new information for investigational and off-label treatment options for COVID-19 (last updated 7/29/2020), which would also include emerging data on hydroxychloroquine use.

VHA PBM Information on Inve

Aside from updating the above document regularly, the following resources related to guidance on off-label prescribing of pharmaceuticals and the safety of hydroxychloroquine/chloroquine are available for use by providers:

Guidance on Off Label Prescribing.pdf

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Medication Safety

Question 19. How can VA be helpful to the international effort to identify a treatment or vaccine for COVID-19?

Response: VA has a significant and unique capability to participate in the international efforts to identify vaccines and treatments for COVID-19. In addition to being the largest integrated healthcare system in the nation, which includes a number of top clinician-investigators and a vulnerable patient population. VA has a robust clinical research enterprise that has been actively engaged in these critical activities. Currently, VA has roughly 40 sites participating in clinical trials being centrally coordinated through its Office of Research and Development. Furthermore, VA is collaborating with federal, academic and industry partners by leveraging its network of clinical trials, epidemiologic, genomics, informatics and health services expertise to help with providing scientific, operational and clinical insights into conducting studies more efficiently. VA is leveraging its own Central Institutional Review Board (IRB) for VHA funded multi-site studies and has entered into service agreements and is relying on commercial IRBs for extramurally funded trials. Reliance on single IRB review is drastically reducing study start up times. Finally, VA has put forth a set of operational and regulatory policies and procedures that allow more a more streamlined ability to partner in multi-site clinical trials to help bring more proven answers on whether treatments and vaccines are effective.

Some more specific VA contributions to national efforts for identifying effective treatments and vaccines are as follows. First, VA is a federal partner in the Operation Warp Speed and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) efforts. VA has coordinated its medical facilities and research infrastructure to these important clinical trials on treatments and vaccines. VA also has nearly 100 sites participating in the Mayo Clinic's national convalescent plasma expanded access protocol to provide Veterans with an opportunity under this effort to evaluate whether those receiving plasma from recovered COVID-19 patients is effective. Over 500 Veterans have received nearly 900 units of convalescent plasma. Additionally, VA is funding its own clinical trials and analyses within the VA health care system. Examples of these trials include one which will examine the potential benefit of the prostate cancer drug, Degarelix, which has suggested possible effects for helping those infected with SARS-CoV2 and a randomized controlled trial of convalescent plasma. VA's Office of Research and Development is supporting a national observational study on inpatients, outpatients and community living center residents to determine risk factors and the course of disease among

those with COVID-19. This study is being done jointly with the Department of Defense. Finally, VA is also conducted a set of analyses using its extensive electronic medical record to look at the safety and efficacy of available treatments for COVID-19 as well as disparities among Veterans to determine whether patterns of care and/or patient characteristics may help better inform how VA cares for those with COVID-19.

Question 20. Is VA's Medical and Prosthetic Research budget sufficient to ensure VA is an active participant in this effort?

Response: VA is currently submitting a legislative proposal allowing funds to be transferred from Medical Services to Research in support of all COVID-19 research efforts, including vaccine development.

At the time of the President's Budget submission, COVID-19 was unknown. Nothing in the research budget address the impacts of this pandemic nor is fully dedicated to realizing VA's potential in battling COVID-19. As noted, VA Research has prioritized available resources in order to maximize its contribution to the national and international efforts to combat the pandemic. However, most of these efforts involve leveraging existing capabilities and reorienting them towards COVID-19-specific activities. As such, some other areas of research in less urgent but none-the-less important to Veterans may be impacted given the projected funding levels. Priority funding to COVID-19 research may limit funding available in other study areas normally supported by the VA research appropriation. VA has consistently developed innovative approaches to doing research in high priority areas given the its uniqueness of having a research program integrated within a national healthcare system. Opportunities to bring these assets together for COVID-19 research include the ability to establish a national biorepository to collect, store and analyze specimens for a large number of patients to understand the mechanisms and pathways of disease particularly for SARS-CoV2/COVID-19 preclinical work. Furthermore, a dedicated clinical research network that can rapidly launch new trials and shift to COVID-19 hot spots can be set up to test new vaccines and/or treatments when ready. In this regard, VA has already been in conversations with other federal and industry groups to partner in clinical trials. This infrastructure would be comprised of dedicated clinical and research personnel, support services (e.g., laboratory, pharmacy), telehealth and other capabilities that represent a targeted expansion for COVID-19 work. Such infrastructure can be established as a stable and connected part of the larger health care system should dedicated resources be available to be put toward that. However, one key need for supporting the research activities that is not part of the VA Medical and Prosthetic Research Budget is accompanying Information Technology (IT) funding to support the number of informatics, data collection and analytic activities needed to effectively inform COVID-19 researchers and clinicians about treatments and other activities in handling the pandemic. For example, VA is aware that limited IT capacity for research activities results in slower completion of critical analyses than for comparable work done by colleagues outside VA. Furthermore, what's needed for COVID-19 research are curated data to allow for a more systematic and efficient approach to conduct large-scale analyses that is more capable of informing the VA healthcare system. Currently, other programs within VA involved in COVID-19 operations and/or research are coordinating with ORD and a greater ability to support IT dependent efforts would help ensure VA can be an active partner in these efforts nationally.

Question 21. The FY20 appropriations bill for VA included $50 million in rescissions from the Medical and Prosthetic Research Program. What research priorities and specific pressing needs does the VA research program currently face that could be supported by re-instating this funding? Please provide a list of research projects that have been impacted by the rescission and what those impacts entail.

Response: Satisfying the $50M rescission required replacing commitments made with FY19/20 funding with FY20/21 funding for equipment, support for various clinical trials, selected merit awards, contracts for the Million Veteran Program, and various agreements. The impact of this funding exchange resulted in less funding being available in FY20 for investment in other critical areas of research to include expanded clinical trials, military exposures, exploring alternatives to sensitive species research, as well as continued efforts on women's health issue and other diversity and equity issues.

Restoration of the $50M would enable VA research to invest significantly in research in all areas associated with environmental and toxic exposure and expand research for potential linkage with rare cancers. Restoration of funding would be most impactful in expanding clinical trials in all areas associated with the national response to COVID-19 as well as supporting expansion and availability of other clinical trials to achieve diversity and equity for all Veterans. Funding would also support the continued effort to expand the Million Veteran Program and ensure the associated data is available to a larger pool of researchers to understand the genetic underpinnings of diseases that disproportionately affect Veterans. These funds will also allow VA to more fully pursue a new initiative focused on the social determinants of health, which will examine comprehensive, innovative community level projects that address the impact of social factors such as income, education, place of residence, and discrimination on health inequities and access to quality care for our Veterans.

Prosthetics

Question 22. What is VA's plan for increasing/expanding VA's prosthetic and orthotic workforce? What is VA's plan for expanding VA-operated prosthetic and orthotic labs?

Response: VA currently has no plans to increase/expand its complement of orthotists and prosthetists (O&P) and its O&P labs. A decision to do so in the future will be guided by the demand and need for such services. For the past three years, VA has conducted workforce analyses for O&P, annually, and submitted reports to Congress. VA has continued to see positive hiring trends of clinical O&P, demonstrating growth annually; e.g., the 13 percent growth of VA clinical O&P staff in the last year (as of June 2020) is well ahead of growth in incident cases of Veterans with amputation (averaging about one percent annually in recent years). VA's National Program Office for O&P supports each VA Medical Center to assure their site leaders have materials to support recruitment and retention of staff necessary to support VA O&P Laboratory facilities; e.g., providing hiring information including professional qualification standards for O&P clinician, sample functional statements, position vacancy announcements, and sample recruiting materials. The VA Office of Academic Affiliations is also conducting a rigorous recompete of the VA O&P residency program to assure residency directors and their programs are recognized by their professional accrediting organization, and are prepared to deliver

approved curricula and enhance potential hiring of O&P residents who are trained within the VA residency training program.

Workforce

Question 23. Given how much the nation has asked of VA staff during this pandemic, and how much we will continue to ask of them, what is VA doing to ease provider burnout and to retain its workforce?

Response: The Department has made considerable efforts in working to reduce provider burnout before, during, and after the current pandemic on numerous fronts. VA policy provides for flexible, compressed and variable work schedules which enable employees to flex their arrival and departure times and/or the ability to schedule their work on fewer than 10 workdays in each pay period. In March 2020, VA implemented a variable work schedule policy which allows full-time physicians the ability to vary the number of days and hours worked each pay period while consistently receiving the salary and benefits of a full-time employee, provided they meet an annual work requirement of 2,080 hours. VA encourages the extension of these flexibilities to the maximum extent possible to allow our physicians the greatest control of their schedule as is possible, within limits, consistent with the duties and responsibilities of their positions.

Wellness is an integral part of VA and the Employee Health & Wellness Program seeks to inspire, motivate and encourage employees to make wellness a priority. This commitment extends beyond physical activity to balanced nutrition, behavioral changes and lifelong wellness management. The VA Employee Health & Wellness Program focuses on the whole health of the employee through targeted articles (e.g., how to avoid burnout); monthly education, awareness, and resources about health topics (e.g., PTSD, minority mental health); and seasonal campaigns intended to support the health and wellbeing of all employees. VA invests in their employees by offering programs that help them achieve healthier, happier lifestyles. VA offers several online learning courses that focus on employee health. In February 2020, a physician engagement toolkit designed to promote awareness of burnout was developed and made available to employees. The toolkit includes resources available to help physicians recognize, manage and reduce burnout in order to live balanced and healthy lives while improving the quality of care for their patients.

A substantial effort has also been made to increase staffing levels across the enterprise; this includes the utilization of delegated hiring authorities, dual compensation waivers, retention incentives, and the implementation of new policies which streamline the onboarding of new employees to address the additional workload placed on existing staff.

Lastly, the VA Employee Assistance Program (EAP) offers free and confidential assessments and counseling addressing issues affecting mental and emotional well-being. EAP services can provide both prevention and early intervention for employees and their families.
VHA is helping employees face these times with support, adaptive coping skills and employing other effective strategies to combat the effects of these difficult times and beyond. Several resources have been developed and made available to employees to help ease burn-out at all levels across the organization. These resources include the launch of a self-care resources for

whole health website, the development of a national toolkit that includes guidance and other resources for local implementation of supplemental local support in addition to Employee Assistance Program services, the continuation of consultative support to leaders aimed at creating an engaged and effective workforce, the development of resources that combine current empirical literature with real-time feedback from field leaders to address building resilience, and the launch of a toolkit to help local leaders effectively communicate with employees about diversity and inclusion.

With increases in work flexibilities and staffing, coupled with the opportunities for counseling via EAP, VA's goal is to help reduce the burden on existing employees and the "burnout" feelings related to the response to COVID-19 within our Veteran community. The Veterans Health Administration's National Center for Organizational Development provides additional resources for employees and leaders on its intranet site.

Question 24. In recent months the Department has been able to get time-to-hire down to just 3 days, from a previous average of 90 days, adding more than 10,000 clinical staff. Does VA plan to sustain this short time-to-hire window, and if so, how? Does VA need any additional resources or authorities to help bring on more staff?

Response: Yes, VA needs additional resources and authorities to help bring on more and retain staff. Given current resources it will be difficult to sustain accelerated hiring. VA used Direct Hire Authorities and temporarily suspended pre-employment processes to streamline onboarding. VA is exploring possible regulation changes to continue onboarding employees before typical pre-employment processes are complete. Pre-employment processes include fingerprints, I-9 verification, personnel suitability, and credentialing. VA's Office of the Chief Human Capital Officer is assembling a multidisciplinary team to assess the feasibility and appropriateness of the continued use of a number of these flexibilities and policy changes. Some of the flexibilities will require statutory or regulatory relief. Congress may be able to assist with approving any proposed relief that VA identifies as the most beneficial in assisting with meeting the needs of our Nation's Veterans, and that would be appropriate for continued use during normal and/or emergency operations.

Overall, time to hire is measured from the "Hiring Need Validated Date" to "New Hire Actual Start Date". OPM's suggested target is 80 calendar days for this measure. The 72-hour time frame is strictly referring to the final steps of the hiring process or the time it takes to onboard an employee, which is the time from when an offer is made until the employee reports to work. Given current resources it will be difficult to sustain accelerated hiring. VA used Direct Hire Authorities and temporarily suspended pre-employment processes to streamline onboarding. VA is exploring possible regulation changes to continue onboarding employees before typical pre-employment processes are complete. Pre-employment processes include fingerprints, I-9 verification, personnel suitability, and credentialing. VA has assembled a multidisciplinary team to assess the feasibility and appropriateness of the continued use of a number of these flexibilities and policy changes. Some of the flexibilities will require statutory or regulatory relief. Congress may be able to assist with approving any proposed relief that VA identifies as the most beneficial in assisting with meeting the needs of our Nation's Veterans, and that would be appropriate for continued use during normal and/or emergency operations.

Most recently, VA submitted COVID-related and permanent proposals that would establish an exception to the hiring requirements under 5 U.S.C. § 3310 for Housekeeping Aids in VA. Excepting VA from this restriction will expedite recruitment and hiring processes for Housekeeping Aids, especially within the Veterans Health Administration.

Emergency Operations

Question 25. How is VA addressing current needs, preparing for a potential second wave of COVID-19 and, getting ready for hurricane season?

Response: VA has experience dealing with consecutive disasters such as in 2017 with the California wildfires and Hurricanes Harvey, Irma and Maria. During those disasters, VA leveraged strategically placed resources and existing programs such as mobile Vet Centers, mobile medical units, mobile emergency nutrition units, outreach to vulnerable patients and mental health counselling to ensure Veterans were able to receive care and other support services. However, a natural disaster during a global pandemic, such as COVID-19, would present unprecedented challenges that we, as a Federal response team, will be required to face using innovative solutions that will not only ensure VA's mission continues, but also that VA serves as one of the cornerstones to the Federal response.

VA's efforts to address current needs, prepare for a potential second wave of COVID and hurricane season are being coordinated through the Crisis Action Team (CAT). The CAT is a committee of senior and key leadership where every administration and staff office are represented. Early consensus was made to establish a "Tiger Team" with the expressed purpose of conducting analysis the VA's ability to maximize telework via virtual connection to VA systems. This team provided a rapid analysis and defined the Departments capabilities to ensure maximum execution of functions in a virtual environment and preserve the health and safety of its workforce. With an increased virtual presence OIT was able to provide updates to the infrastructure and accommodate the increased number of gateway users.

Through the VAIOC (Veterans Affairs Integrated Operations Center) a partnership was established for information sharing with Johns Hopkins and University of Maryland where public health and epidemiological statistical reports were provided to allow for the creation and use of "VA COVID-19 Reopening Analysis Model" to provide informative decision making while providing the flexibility to complete functions while ensuring the health and safety of the workforce. VAIOC is remaining vigilant in its interagency participation through the Nation Response Coordination Center (NRCC) and relevant working groups.

VHA, Office of General Counsel and Office of Chief Human Capital Officer were successful in quickly compiling and sharing COVID-19 FAQs and human resources policy updates and coordinate with Office of Personnel Management the use of any special authorities to drive informative decision making by leaders at all levels. VA's Office of Acquisition, Logistics and Construction has also coordinated and established relationships with manufacturers, retailers, and logistics suppliers to ensure that the VA has the appropriate levels of resources, when and where

necessary. Department level plans and policies are being made Pandemic relevant through review and updates.

Public facing service facilities are being equipped with customer service updates such as pertinent signage, sneeze guards/shields, and other sanitation equipment. Facilities and campuses have standing policies addressing temperature checks prior to entry and the ability to ensure physical distancing.

VA has a series of emergency management and disaster response plans. VA published the Disaster Response During A Pandemic plan that supports an all-hazards response during the COVID-19 pandemic, with a focus on hurricanes. The plan emphasizes VA's health care preparedness and response to a hurricane complicated by the global pandemic COVID-19. The response plan focuses on protecting Veterans, their families, caregivers and VA staff members.

The response plan is based on a three-phase operation with each phase having objectives and trigger points that will inform decisions. The plan incorporates practices, protocols, and procedures developed during the initial COVID-19 outbreak. The plan provides responses and includes identifying critical considerations for conducting response operations to a hurricane within the COVID-19 environment.

The plan was socialized with each Veterans Integrated Service Network and VA Medical Center Director. A Tabletop Simulation Manual – Response to an Advance-Notice Incident During COVID-19 has been shared and provides guidance on how each facility should respond to events during the COVID-19 Pandemic.

The core capabilities require:

- The facility to implement processes and procedures to make notifications and conduct initial response and assessment
- The facility to manage incidents in accordance with National Incident Management System principles
- The facility to implement processes and procedures to evacuate patients, visitors and staff
- The facility to implement procedures for incident demobilization and recovery

The objectives of the Tabletop exercises are:

- Evaluate conditions that impact the decision-making process regarding response to an advance-notice all-hazard disaster occurring during a pandemic event. Generate discussion regarding these conditions and identifying thresholds (trigger points) that necessitate key decisions and the resulting actions
- Patient evacuation planning – The Incident Management Team is capable of segmenting and tracking Vulnerable Patients (including COVID and non-COVID Patients) during a full VAMC campus evacuation
- Coordination of additional resources – The Incident Management Team can outline the logistical process of overall equipment and resources such as PPE, medical transports, and personnel such as DEMPS during an incident during a pandemic
- Re-Entry & Recovery Planning – post incident; The Incident Management Team can determine the planning factors for patient and staff re-entry to a facility

The Veterans Health Administration Office of Emergency Management's Emergency Management Coordination Cell (EMCC) was activated to full strength on January 20, 2020 and remains fully activated. The EMCC monitors the active Mission Assignments (MA) daily. VHA is committed to 23 Missions currently. VA is actively involved in coordinating all requests for PPE, supplies, personnel, etc., in support of VHA internal and external (4th Mission) requirements.

The EMCC monitors the daily wildfire, seismic and tropical activity, in addition to any civil unrest that may impact VHA's ability to provide care and provides VHA leadership with updates and action plans as needed. The EMCC is poised to respond to any additional threats while maintaining command and control operations on the overall COVID response. The EMCC will convene senior leadership and all VHA VISNs, VAMCs and Program Offices at a moment's notice in the event of an urgent requirement to respond to an emergency across the VHA enterprise.

Question 26. Does the Department need additional resources or authorities for its Emergency Operations or Fourth Mission functions? How will VA balance these responsibilities in the months to come?

Response: No additional resources or authority are required to execute VA's Fourth Mission or Emergency Operations at this time. We appreciated the opportunity to receive supplemental funding from the CARES Act to enhance our capabilities and the ability to meet our 4th mission. VA will continue to balance responsibilities through the Crisis Action Team (CAT) where department-level synchronization and decision making occurs for incident response efforts. VA is billing FEMA for care delivered through specified mission assignments and anticipates timely reimbursement. VA will continue to monitor and notify Congress should estimates change.

Electronic Health Records

Question 27. How will VA balance re-starting implementation of the new health record at VA health care facilities, with the health and wellbeing of the VA workforce?

Response: The safety and care of our Veterans and staff remains VA's highest priority. OEHRM is developing re-entry strategies, aligned with local health guidelines, as access is granted by facility and VISN leadership, based on minimal COVID-19 impacts and staff bandwidth. During re-engagement, OEHRM will remain conscious of the prioritization of facility and staff engaged with COVID-19 and will remain flexible through the transition to VA's new EHR solution. OEHRM will follow strict safety protocols when engaging with facility staff. Additionally, OEHRM is evaluating the expansion of virtual training platforms to decrease in-person contact to decrease in-person contact further promoting adherence to social distancing guidelines.

Question 28. Given the delays in implementation, does VA still anticipate needing $2.6 billion in FY21 for EHRM?

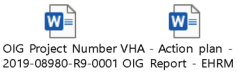
Response: VA still requires $2.6 billion to support the Electronic Health Record Modernization (EHRM) effort in fiscal year (FY) 2021. In order to optimize the utilization of resources and minimize the impacts of COVID-19, OEHRM is revising the EHRM deployment strategy to maximize implementation efforts in areas where there have been minimal COVID-19 impacts. OEHRM plans to pull forward FY 2021 costs into FY 2020 for items essential to wave implementations, such as software license expenses, registries, deployment servers and pre-purchasing of equipment. VA will also invest in virtual training platforms and computer-based training to meet VA's needs. This plan preserves the 10-year deployment timeline and overall Life Cycle Cost Estimate (LCCE).

Question 29. In light of VA's previous efforts related to EHR, what is the Department's plan for reliably identifying and reporting the total costs of the new health record system?

Response: The OEHRM Program Management Office (PMO), is responsible for providing oversight of program's adherence to cost, schedule and performance objectives while mitigating risks. The PMO employs highly trained government and contractor personnel to provide expertise in a myriad of professional disciplines, enabling the program to reliably report the total cost of the EHRM effort. The personnel actively manage the program's funding allocation to ensure it adheres to the LCCE and continuously validates funding requirements shared by Cerner.

Question 30. What progress has the Department made in addressing the recommendations from the two Inspector General reports, released this spring, on infrastructure and staffing needs for electronic health record modernization?

Response: Attached are the action plans developed by VA in response to the two Inspector General reports.



National Guard

Question 31. It is the Committee's understanding that different types of orders from the federal government will grant different benefits, causing National Guardsmen to serve side-by-side with their active-duty counterparts even though they may not be receiving the same GI Bill benefits, retirement credits, or legal protections for themselves and their family members. Does VA agree that this is an accurate description of the circumstances under which VA is obligated to provide benefits to Members of the National Guard?

Response: Most National Guard (NG) and reserve component members are eligible for some VA benefits. However, the VA benefits and services available are dependent upon factors such as the type of duty that was performed, the specific call up authority he or she was under when performing such duty, and the final characterization of the service.

For example, VA's authority to provide disability compensation benefits is limited to individuals who have "served in the active military, naval, or air service, and who was discharged or released therefrom under conditions other than dishonorable." (38 U.S.C. 101(2)) The statue further specifics that the term "active military, naval, or air service" can include periods of active duty, active duty for training, or inactive duty for training when additional criteria are met, such as when the individual concerned was disabled or died from an injury incurred or aggravated in the line of duty. (See generally 38 U.S.C. 101(24))

To illustrate this concept, generally, NG or reserve members who are deployed and/or performing federal full-time duty under title 10 United States Code, would be eligible for the same benefits as their active-duty counterparts assuming that all other eligibility requirements are met. However, this would not be the case for NG members who are ordered to non-federal full-time duty under state active duty. In this regard, VA has no authority to provide federal benefits based on state duty.

As another example, if NG members are performing full time duty, under state authority but authorized under title 32, section 502, this type of duty is typically considered active duty for training. While this duty does not automatically establish eligibility under 38 U.S.C. 101(2), it might meet the definition of "active military, naval, or air service" if other criteria are met, such as those noted above.

Active military, naval, or air service includes active duty and may include active duty for training (ADT) or inactive duty for training (IADT). ADT or IADT would only qualify for purposes of meeting wartime service requirement for pension benefits if:

- the Veteran was granted SC conditions due to ADT/IADT
- was discharged or released for a disability incurred in or aggravated by service or would have justified discharge, AND
- the IADT/ADT occurred during a wartime period

Under current law, non-Federal service, such as State Active Duty, does not establish Veterans status. State Active Duty is full-time duty in the State military forces under an order of the local Governor or otherwise issued by authority of local State law and paid by State funds.

Typically, individuals who are disabled based on State service are compensated based on State law. Historically, VA has opposed payment of disability compensation for individuals who are locally compensated by their individual States and who were not injured due to Federal Service.

Question 32. Does VA agree that it should be providing survivors benefits to family members of National Guardsmen who contract COVID-19 in the line of duty and lose their life to the illness, regardless of their duty status?

Response: Unless the service by a National Guardsmen is considered to be federal active service, VA benefits would not be applicable. Under current law, non-Federal service, such as

State Active Duty, does not establish Veterans status. State Active Duty is full-time duty in the State military forces under an order of the local Governor or otherwise issued by authority of local State law and paid by State funds.

Typically, survivors of National Guardsmen who die as a result of State service are compensated according to State law. Historically, VA has opposed payment of compensation for survivors who are locally compensated by their individual States and who did not die as a result of Federal Service.

Question 33. Does VA agree that it should provide all of the same benefits to the National Guardsmen that are serving side-by-side with active-duty troops, wherever they may be, as long as they wear the uniform of the United States Military?

Response: See prior response. VA provides benefits and services to individuals in accordance with established laws and regulations.

Senator Brown

Congress passed the Economic Growth, Regulatory Relief, and Consumer Protection Act on May 25, 2018. This law included a provision that limited VA guarantees on Interest Rate Reduction Refinance Loans (IRRRLs) to loans that have "seasoned" for at least 210 days or six monthly payments and to meet certain recoupment, net tangible benefit, and payment tests. These provisions were effective immediately. On April 20, 2020, VA issued Circular 26-20-16 instructing VA lenders that they must submit lists of non-compliant IRRRLs they've issued. The circular specifically requires lenders to report noncompliant loans that were issued a year or more after the Economic Growth, Regulatory Relief, and Consumer Protection Act passed and to take action to cure these loans.

Question 1. Why did VA issue this circular? What information or data did VA have about the number of noncompliant loans? Please include the number of outstanding noncompliant IRRRLs VA is aware of.

Response: VA published Circular 26-20-16, Guidance for Noncompliant Interest Rate Reduction Refinance Loans (IRRRLs), to advise lenders of VA's expectations regarding loans that fail to meet the statutory requirements set forth in section 309 of Public Law 115-174, The Economic Growth, Regulatory Relief, and Consumer Protection Act (the Act). The Circular also reminded lenders of their longstanding obligation to report non-compliant loans as provided in Chapter 5, Monitoring Unit, of VA M26-9, Quality Control Procedures Loan Guaranty Operations for Regional Offices

VA evaluated the requisite loan data collected from lenders when requesting the VA Loan Guaranty Certificate for Interest Rate Reduction Refinance Loans (IRRRLs). Given the new requirements established under P.L. 115-174, VA determined that it could not conclusively determine if a loan was non-compliant without engaging lenders directly on a loan-by-loan basis. VA leveraged the data available to determine if an IRRRL was potentially non-compliant.

Initially, VA identified 22,132 potentially non-compliant IRRRLs guaranteed between the passage of P.L 115-174 on May 18, 2018 and the effective date of Circular 08/28/2019, Clarification and Updates to Policy Guidance for VA Interest Rate Reduction Refinance Loans. A total of 480 out of nearly 1,500 lenders were identified as having a non-compliant loan. Of the 22,132 potentially non-compliant IRRRLs: 21,584 (98 percent) failed fee recoupment; 544 (2 percent) failed the Net Tangible Benefit (NTB) test; and four failed loan seasoning.

VA issued lender-specific letters identifying the potentially non-complaint IRRRLs, in addition to conducting individual phone calls with the top 10 lenders with the highest volume of potentially non-complaint IRRRLs. Using this data, VA created a specialized team to focus on working with lenders to determine which loans were incorrectly identified as non-compliant due to data entry errors on the part of the lender. In addition, the specialized team was tasked to focus on loans that were in fact non-compliant, review and monitor loan-level cure plans, and/or collect loan-level indemnification agreements for loans that could not be cured.

As of July 10, 2020, the specialized team completed work with 477 of the 480 lenders included in this effort. Of the 22,132 IRRRLs identified as possibly non-complaint, VA reviewed 16,305 and determined the loans have been successfully cured or are compliant with VA requirements. VA concluded that approximately 80% of potentially non-compliant IRRRLs that failed fee recoupment were attributed to incorrect data entry into VA systems. We estimate that approximately 1,200 of the 22,132 loans originally identified are outstanding. Three remaining lenders originated the 1,200 loans that are possibly non-compliant. VA continues its engagement with these three lenders and expects a timely resolution of any outstanding deficiencies. Since the initial review of VA IRRRLs, VA systems have been enhanced to assist lenders in calculating fee recoupment and reduce data entry errors.

Question 2. Why, more than two years after the 2018 law passed, is there such a volume of noncompliant loans being issued that VA requires quarterly reporting? Are there any other areas circumstances in which VA requires quarterly reporting of noncompliance with its lending requirements?

Response: On May 20, 2018, prior to signing of the Economic Growth, Regulatory Relief, and Consumer Protection Act, VA proactively made system enhancements to allow for the review and identification of potential non-compliant IRRRLs. Through routine audits and self-reporting, VA identified potential IRRRLs that did not meet the statutory requirement(s) and contacted affected lenders about efforts to cure the non-compliance. However, the VA system was not fully configured to anticipate the provisions of P.L. 115-174 in order to prevent lenders from securing a VA Loan Guaranty Certificate (LGC), despite potential non-compliance. VA has since made significant investments in preventative and proactive controls for non-compliant IRRRLs. These enhancements were deployed on March 19, May 2, and July 12, 2020.

Typically, lenders report non-compliant loans on a loan-by-loan basis as they are discovered. On August 8, 2019, VA published Circular 26-19-22, Clarification and Updates to Policy Guidance for VA Interest Rate Reduction Refinance Loans (IRRRLs), authorizing lenders to take steps to cure non-compliant IRRRLs without VA's prior approval, provided that such action(s) does not result in additional cost to the Veteran. However, due to the nature of loan seasoning requirements, cure action(s) is not possible. Circular 26-20-16 provides VA the needed ability to distinguish between non-compliant IRRRLs and other non-compliant loans self-reported by lenders.

Per Circular 26-20-16, the first mandatory quarterly reporting of all non-compliant IRRRLs with an application date on or after May 25, 2018, was July 1, 2020. A total of 34 lenders reported one or more non-compliant IRRRLs during the reporting period. Approximately 490 IRRRLs were reported as being non-compliant. VA anticipates a further decline in non-compliant loans in subsequent reporting periods once the impact of the most recent system enhancement is fully realized, alongside further clarifications concerning the calculation of recoupment.

The quarterly reports required by Circular 26-20-16 identify non-compliant IRRRLs in bulk, which will assist VA in deploying an expedited process by which lenders may proactively volunteer to execute an indemnification agreement, as applicable. An indemnification agreement allows VA to recoup expenses and losses associated with a foreclosure claim or preclude VA

from paying a claim in certain circumstances. The expedited process will ensure a more timely and efficient execution of indemnification agreements.

Question 3. What requirement from the Economic Growth, Regulatory Relief, and Consumer Protection Act (including net tangible benefit test, payment amounts, seasoning requirements, and any other requirements enacted in 2018, as amended in 2019) is most common in noncompliant loans?

Response: A total of 490 IRRRLs were reported as non-compliant for the period of April 1, 2020 through June 30, 2020. Of the 490 non-compliant IRRRLs reported by lenders in accordance with Circular 26-20-16, 117 were reported as failing seasoning, 293 were reported as failing recoupment, nine were reported as failing the NTB test, and 71 were reported as failing other requirements under P.L. 115-174.

Question 4. How quickly will VA require lenders to cure or indemnify VA for noncompliant loans?

Response: VA requires lenders to cure and/or indemnify non-complaint loans within a reasonable timeframe. Generally, VA encourages these actions to be completed within 3 months of identification. Lenders are encouraged to be transparent and communicative throughout the cure/indemnification process. For loans requiring extraordinary analysis, effort, etc., VA will work with lenders to ensure a timely resolution.

Question 5. What are the consequences for lenders that repeatedly violate the 2018 law's limits on IRRRLs and cash-out refinance transactions? Please provide all options available to VA and the number of times VA has used any of these options since the 2018 law passed.

Response: Lenders found to repeatedly violate any VA statute, VA regulations or VA policy may be subjected to a variety of corrective actions available to VA. These include, but are not limited to, special audit; temporarily withdrawal of a lender's automatic authority to guarantee loans on an automatic basis; and, suspension and/or removal from the program.
In instances related specifically to non-compliance with P.L. 115-174, VA may also notify all affected Veterans of the lender's decision not to cure their IRRRLs. VA may also include public communications to all Veterans and other stakeholders that a lender's automatic authority has been temporarily withdrawn and that, due to such, loan closings will likely be subject to indefinite delays. This is because VA has limited resources available for processing loan files submitted to VA for prior loan approval. VA may also work with its government partners, such as the Consumer Financial Protection Bureau (CFPB) and Government National Mortgage Association (Ginnie Mae), to determine if further action is appropriate when a lender chooses not to cure any noncompliant IRRRLs.

To date, VA has not had to take any of the aforementioned actions against our lender partners as a result of non-compliance with P.L. 115-174, since lenders are working to correct any identified deficiencies. VA will continue to closely monitor lenders for compliance and will take the appropriate actions as deemed necessary.

Question 6. What is the update on adding Parkinsonism, Bladder Cancer, Hypertension, and Hypothyroidism to the list of Presumptive Health Outcomes in connection to Agent Orange exposure?

Response: In determining whether to add a disease to the list of those conditions presumptively associated with exposure to Agent Orange, VA considers all sound medical and scientific evidence.

VA has granted service connection for Agent Orange presumptive conditions since 1991, when the Agent Orange Act was signed into law. Since then, VA has recognized 14 diseases and cancers presumed to be caused by Agent Orange for Veterans who served in Vietnam. In addition, this year VA implemented the Blue Water Navy Vietnam Veterans Act of 2019, which extends presumptive disability benefits for Veterans who served in the offshore waters of the Republic of Vietnam.

Currently, VA's Office of Research and Development is conducting two studies - the Vietnam Era Health Retrospective Observational Study (VE-HEROeS) and the Vietnam Era Mortality Study - that may provide additional insight into the relationship between Agent Orange exposure and hypertension, hypothyroidism, bladder cancer, and Parkinsonism.

The Secretary of Veterans Affairs will review all relevant studies as well as the work of a VA medical committee and determine whether these associations are sufficient to add hypertension, hypothyroidism, bladder cancer, or Parkinsonism to the list of diseases presumed to be associated with Agent Orange exposure. Once a decision has been made, it will be made available to the public. The Secretary remains committed to granting presumptive status for new conditions if and when the research establishes a positive association between the condition and Agent Orange exposure.

Question 7. OEHRM and Cerner were set to deliver the Centralized Scheduling Solution (CSS), a new patient appointment management component of the modernized EHR, to the Chalmers P. Wylie VA Ambulatory Care Center in Columbus, Ohio, in April. However, it was postponed because of the COVID-19 pandemic. What is the status of the EHR and CSS implementation?

Response: Based on ongoing COVID-19 impact assessments and frequent interactions with medical staff, VA plans to focus on the implementation of the Centralized Scheduling Solution (CSS) in Columbus, Ohio, while the staff in the Pacific Northwest address emergent COVID-19 cases. As an ambulatory care center focused on outpatient services, COVID-19 has less impact on the Columbus facility and CSS deployment activities, facilitating adherence to social distancing requirements, e.g., trainees and training space, due to the size of the facility and scope of the capabilities to be deployed. Access to the Columbus facility was authorized on June 22, 2020, beginning the one-week assessment period on the path to CSS Go-Live.

Question 8. Will VA use virtual training to move forward with go-lives dates, or will VA use in-person training?

Response: VA will offer virtual training for all levels of staff in the at-risk population. To limit in-person contact, VA is piloting virtual training with a small cohort of end users at the Columbus facility to assess the feasibility of this modality for other user roles and deployments. Other end users will attend in-person training, following strict safety measures and adhering to social distancing requirements.

Question 9. What safety measures will the Department use when in-person training resumes?

Response: When in-person training resumes, VA will adhere to the following safety measures:

1. Reduce class sizes from 15 to 7 end users with one instructor and one super user, with a maximum of 10 people per room
2. Limit the number of contact points, ensuring end users are placed in cohorts so that all training will be taken with the same group
3. Exclude unregistered participants from entering classrooms during sessions
4. Require all participants to wear masks during training sessions
5. Provide hand sanitizer and wipes in training classrooms
6. Clean training rooms and equipment between sessions
7. Adhere to safety protocols established by local facility leadership
8. Maintain class rosters to allow for contact tracing

Question 10. On May 29, 2020, President Trump issued his first veto of domestic policy and overruled H.J.Res. 76, bipartisan legislation that would overturn the U.S. Department of Education's harmful 2019 Borrower Defense Rule. H.J.Res. 76 would overturn the 2019 borrower defense rule which would make it harder for defrauded student loan borrowers, including veterans and their families, to get loan relief they deserve and would roll back accountability measures meant to protect students and taxpayers.
Too often, veterans and military families are targeted by online and for-profit schools with misleading marketing, saddling students with mountains of debt and near-worthless degrees. H.J.Res. 76 had widespread bipartisan support and over 30 veterans' organizations called on the president to sign the bill into law.

Just days after Memorial Day, President Trump issued his first veto on domestic policy to make it harder for veterans defrauded by their college or university to get the loan relief they're entitled to. Did President Trump or the White House ask for additional information on the impact the 2019 borrower defense rule would have on student veterans or consult you or the VA as he considered his veto? If so, please detail those interactions.

Response: Education Service did not receive a request for information on the impact of the 2019 Borrower Defense Rule.

Question 11. Congress provided the Department with over $19 billion for medical services and IT support in the CARES Act. Please provide data for the following questions related to expanding video and connectivity capabilities for veterans who want to use telehealth.
How much CARES Act funding has been obligated related to telehealth and for what specific programs?

Response: Telehealth obligations totaled just under $41 million as of the end of June.


Telehealth Expense Tracking - COVID-19

Question 11a. Of the funding obligated, how much has been spent and what is the Department's plan for the unobligated funds?

Response: VA has expended $1.26 billion of CARES Act funding through June 30, 2020. VA plans to use the remaining funds to care for Veterans impacted by COVID-19, including procuring equipment and supplies at VA hospitals, maintaining expanded telehealth capabilities, and providing support for Veterans experiencing or at risk of homelessness due COVID-19.

The attached spreadsheet contains the VHA spend plan for the CARES resources through the end of FY 2021 and shows execution against that plan as of the end of month June. VA will continue to monitor and notify Congress should estimates change.


09 - EOM June Spend Plan for Shar

Question 11b. Please explain the VAMC approval process if a facility wants to expand telehealth for patients?

Response: VA maintains Telehealth Operations Manuals that provide guidance on obtaining approval to initiate or expand telehealth services. The manuals list steps for planning and development, needs assessments, business case development, and obtaining final approval for implementation and sustainment. Additionally, VA provides telehealth training guides and quality reviews to assist with initiating or expanding telehealth services.

Question 12. During your testimony, you discussed VA's expanded use of telehealth during the pandemic. Please breakdown the number of each specific type of telehealth appointment- video call, telephone, text message?

Response:

Video Call: VA's use of telehealth during the pandemic was focused on providing quality clinical care while promoting social distancing to ensure the safety of both Veterans and health care professionals. Telehealth modalities that required a Veteran to come into a facility such as Clinic-to-Clinic video conferencing and Asynchronous telehealth (Ex. Tele-Dermatology) saw a decrease in utilization. This decrease was more than overcome by the increase in Clinical Video into the home or VVC. Comparing the first 5 months of this fiscal year (October through February) with the 4.5 months starting in March:

- Use of Synchronous Clinical Video visits increased by more than 1.3 million visits or 207%. Use of Clinical Video visits into Veterans homes, which is a subcomponent of all CVT, increased by 890%
- Asynchronous Store and Forward visits decreased by 102,500 visits. This frequently requires a Veteran to come into a facility for specialized imaging. Asynchronous telehealth implemented a protocol to obtain images from home during this time, and this has been utilized when appropriate.
- The net change of both modalities was an increase of more than 1.2 million visits or 146 percent.

Remote Patient monitoring is a program where the Veterans are enrolled and is not visit based. The Veteran responds daily with biometric data as well as answers questions on their health status. Since the arrival of COVID, specific Disease Management Protocols were developed that monitored Veterans for the symptoms related to COVID. Through July 13, 2020, more than 5,000 Veterans were able to be monitored daily for COVID symptoms using this program.

Telephone: VA was able to leverage virtual care though telephone encounters to treat Veterans during the pandemic without the need for Veterans to come in person for their care. VA provided continuity of care to Veterans during this time even in the absence of many in-person appointments.

Comparing the first five months of this fiscal year (October through February) with the 4.5 months starting in March:

- Telephone encounters increased by 8,373,880 or 131%.
- VA completed 14,756,154 telephone encounters from March 2020 to mid-July 2020 compared to 6,382,274 encounters from October 2019 to February 2020.
- VA plans to continue to utilize telephone care when clinically appropriate to ensure Veterans and staff remain safe while getting care needs met.

Text Messaging: Annie: Annie is VA's text messaging service designed primarily for Veteran self-management. Veterans can self-enroll in protocols designed to assist with Coronavirus prevention and coping, tobacco cessation, oncology symptom reporting and weight management. VA staff can enroll patients in over 200 protocols to provide simple reminders or to help manage health conditions including hypertension, diabetes, sleep disorders, Hepatitis A, B, and C, asthma, Coronavirus Isolation/Quarantine, and advanced liver disease. Three protocols were developed specifically for Coronavirus: Precaution, Isolation/Quarantine, and Coping during COVID. The time period for protocols varies and patients can be re-enrolled if desired. Patients may also be enrolled in more than one protocol simultaneously. Currently, 23,626 Veterans are

enrolled in the Annie system and 17,230 are actively participating by using at least one protocol. This represents an increase of 222% since March 30, 2020.

In late April, VA sent a questionnaire to approximately 4400 Veterans enrolled in the Coronavirus Precautions Protocol (CPP). Key findings from the 1159 responses showed the following:

- 885 (76%) report they would have reached out to VA in at least one way (secure message, phone call, visit OR some combination of those) if they had not been on the CPP.
- 204 (18%) report they would have interacted (called or sought care) in the community.
- 681 (59%) report they felt more connected to VA because they received the Annie messages.
- 266 (23%) report they opted not to call or seek care from VA or the community because Annie provided the information they sought.

VA Health Chat: VA is piloting VA Health Chat at two facilities in VISN 23 (Minneapolis and St. Cloud) and throughout VISN 8. Clinical chat provides Veterans access to a VA resource via chat messaging using their mobile device or computer as an alternative to voice (telephone). Since inception (2019 for VISN 23 and mid-February 2020 for VISN 8), VA has received 4,456 chats from 3,869 individual Veterans. This represents an 84% increase in the number of users since March 10, 2020. Veteran satisfaction data show the following:

VISN 23 Veteran Satisfaction Survey* (100 total responses)

- 89% said VA Health Chat improved access to care
- 45% would have sought a PCP or specialty appointment or visited the Emergency Department or Urgent Care if Chat hadn't been available
- 97% were satisfied using VA Health Chat
- 93% would recommend VA Health Chat to a friend

VISN 8 Veteran Satisfaction Survey* (213 total responses)

- 91% said VA Health Chat improved access to care
- 40% would have sought a PCP or specialty appointment or visited the Emergency Department or Urgent Care if Chat hadn't been available
- 95% were satisfied using VA Health Chat
- 95% would recommend VA Health Chat to a friend

*Data from 7/6/2020

Question 12a. Do any of these specific modes collect data on the veteran, or does the clinician have to collect that data and input it later?

Response: The Remote Patient Monitoring – Home Telehealth Program technologies collect and document biometric data and other health information about the Veteran. The data and information are securely transmitted through VA servers for Care Coordinator review and validation and then electronically posted in the Veterans medical record. This process saves time and helps to greatly reduce manual entry error. Store and Forward telehealth technologies also collect data on the Veterans so it can be interpreted by a provider at another location and/or another time. Various other technologies rely on the provider to obtain the information directly from the Veteran before documenting it in the medical record.

Annie: Annie is VA's text messaging service designed primarily for Veteran self-management. Veterans can self-enroll in protocols designed to assist with Coronavirus prevention and coping, tobacco cessation, oncology symptom reporting and weight management. VA staff can enroll patients in over 200 protocols to provide simple reminders or to help manage health conditions including hypertension, diabetes, sleep disorders, Hepatitis A, B, and C, asthma, Coronavirus Isolation/Quarantine, and advanced liver disease. Annie is one of over twenty mobile medical apps that VA has developed to support clinical care. Many of these mobile apps collect patient generated data entered by the patient in the app, or collected from a connected health device that is paired to an app. This data is available for viewing by clinical teams using staff-facing applications. Data transmission is fully encrypted, meeting all government security regulations and stored in a secure VA database.

Question 13. In your testimony, you tout the expanded use of VA Video Connect (VVC) during the pandemic, we have heard anecdotally that there have been technical issues with the VVC platform. Do you have data on how many VVC connections failed during this time, and if connection failed, how were veteran medical needs addressed? What steps have you taken to address the system issues?

Response: When any technical issue with VVC has occurred, the engineering team has evaluated, and where possible, implemented steps to prevent similar future occurrences. Each of the three major service interruptions that have occurred since 2017 were due to external support services interruptions and not as a result of the actual VVC platform. Other reported issues were found to be individual connection challenges into the service (i.e., the patients or providers cell or Wi-Fi service external to the VA network). VA's IT support team cannot take direct action on these instances and have not been specifically tracked for metrics.

During the early stages of our COVID-19 response, VA identified stabilization and enhancement of the existing on-premise VVC system as a key priority. The VHA and OIT Joint Telehealth COVID-19 response team enhanced the VVC scheduling system which allowed bulk scheduling of Virtual Medical Rooms, and added capacity to both Care1 and added Care2 for VVC which increased capacity to 15,200 concurrent calls by adding 78 conference nodes through Care2 and increasing Care1 to 191 conference nodes across 102 servers (pre-COVID on-premise was 64 nodes across 32 servers). OIT also implemented increased monitoring to several key components of the VVC delivery system. This has led to a marked increase in the stability of the system, reducing the number of recorded minutes of downtime.

- Has VA reached out to homeless shelters to test veterans for COVID-19? If so, has VA then treated those homeless veterans for COVID-19 and provided them with VHA benefits?

Response: The VA HPO supports testing of Veterans residing in congregate settings for early identification of COVID-19 cases and to aid in mitigating disease outbreaks in these high-risk locations. Every VAMC has homeless program outreach teams that continue to provide outreach services to non-VA funded homeless shelters, to link homeless Veterans with VHA resource and services.

An Assistant Under Secretary for Health for Operations memo and corresponding SOP regarding HPO's proposed SARS-CoV-2 universal testing protocol for Veterans in GPD and HCHV CRS programs has been developed and is currently under review. The testing memo and SOP provides the requirement that VAMC identify a COVID-19 testing team to conduct testing prior to program admission and on an ongoing basis for Veterans currently enrolled in GPD and HCHV CRS and are eligible for VHA care. The COVID-19 testing team must consist of at minimum one VHA provider for ordering of the test and provision of follow-up care. Additional recommendations in the proposed memo and SOP include the following: 1) coordinate testing events on site using the COVID-19 testing teams, rather than transporting Veterans to local VAMCs, to reduce the chance of disease transmission and increase access, 2) conduct testing events on weekends rather than weekdays to enhance access to testing for Veterans who may lack transportation or work primarily during the weekdays, and 3) include staff from Homeless Patient Aligned Care Teams (H-PACT) for COVID-19 testing teams when possible.

Senator Blumenthal

CARES Act Funding

Question 1. What amount of the funding provided to VA in the CARES Act has been obligated as of 6/1/2020?

Response: VA obligated $2.01 billion of CARES Act appropriations as of 6/1/2020; and a total of $2.69 billion as of 7/1/2020.

Question 2. What amount of the funding provided to VA in the CARES Act has been spent as of 6/1/2020?

Response: VA spent $795 million through the end of May 2020; and $1.26 billion through the end of June 2020.

> *Question 2a.* What has the funding in the CARES Act been spent on? Please specify line item, account, program, office.

Response:

CARES Act Obligations as of July 1, 2020 (Amounts in Millions)		
Program	**Major Object Class**	**Total Obligations**
VHA	10 - Personnel Service	$437.36
	21 - Travel Personnel	4.21
	22 - Transportation	1.97
	23 - Rent, Communication, Utilities	5.35
	24 - Printing & Reproduction	0.09
	25 - Other Services	199.91
	26 - Supplies & Materials	656.51
	31 - Equipment	404.59
	32 - Land & Structure	10.41
	33 - Investments and Loans	0.02
	41 - Grants, Subsidies & Contrib	214.25
	42 - Insurance, Claims & Indemn	0.00
VHA Total		**1,934.67**
OIT	10 - Personnel Service	2.91
	23 - Rent, Communication, Utilities	0.12
	25 - Other Services	407.94
	26 - Supplies & Materials	0.03
	31 - Equipment	339.77

OIT Total		**750.77**
VBA	21 - Travel Personnel	0.07
	22 - Transportation	0.00
	24 - Printing & Reproduction	0.00
	25 - Other Services	0.39
	26 - Supplies & Materials	4.24
	31 - Equipment	0.05
VBA Total		**4.75**
GenAd	10 - Personnel Service	0.09
	25 - Other Services	0.36
	26 - Supplies & Materials	0.28
GenAd Total		**0.73**
OIG	10 - Personnel Service	1.15
	25 - Other Services	1.31
	26 - Supplies & Materials	0.01
	31 - Equipment	0.02
OIG Total		2.49
Grand Total		**$2,693.42**

Question 3. If all funds provided to the VA in the CARES Act are not spent this fiscal year, what are VA's plans for the funds that are not obligated or spent?

Response: CARES Act funds are available through September 30, 2021. VA anticipates executing these funds in support of the ongoing COVID-19 response and will continue to use these funds for that purpose in 2021.

Questions 3a. In which account will these unobligated and unspent funds be transferred?

Response: VA seeks transfer authority to allow medical care funds to be transferred to Veterans Benefits Administration, National Cemetery Administration, and Board of Veterans Appeals to support overtime requirements to address backlogs that have grown as a result of COVID. VA also seeks to transfer funding to VBA and OIT to support modernization of the Education Benefits claims processing system.

As a result of COVID-19, the Veterans Canteen Service (VCS) has experienced a loss of revenue as a result of a 52% decline in customer traffic. VA proposes to transfer up to $140 million to sustain VCS operations from VHA CARES Act funding.

Emergency Care Reimbursement

Question 4. Are the funds necessary to reimburse veterans for emergency care at non-VA facilities as ordered in the Court of Appeals of Veterans Claims *Wolfe v. Wilkie* case included in the FY21 budget request?

Response: Funds to support the Wolfe v. Wilkie were not included in the FY 2021 budget submission.

Question 4a. From what accounts will this money be taken?

Response: Monies to reimburse the Veteran for emergency care at non-VA facilities consistent with the Wolfe decision would come from Medical Community Care account. Monies will come from Medical Community Care account and Medical Support and Compliance (administrative costs for implementing).

Question 4b. How much does VA anticipate spending to reimburse these claims?

Response: VA does not have a current estimate of the cost of Wolfe v. Wilkie. VHA is evaluating Wolfe's retroactive and FY 2021 cost estimates using the limited historical claims data that is currently available.

Mental Health/Suicide Prevention Funding

Question 5. VA's budget request includes an increase of $682 million for mental health and suicide prevention programs. Which mental health programs will receive an increase in funding for FY 2021?

Response: Mental health care at VA comprises an unparalled system of comprehensive treatments and services to meet the needs of each Veteran and the family members involved in their care. The continuum of VHA mental health care spans from self-help protocols (e.g., smart phone apps), to outpatient care, employment support, intensive outpatient treatment, residential care, and acute hospitalization. Veteran demand for VHA mental health services continues to grow, with approximately 1.8 million Veterans (29 percent of all VHA users) seeking care in 2019.

Historically, VA has been primarily focused on internal strategies to reach Veterans within our system for suicide prevention. However, VA's current actions and future vision for reducing suicide among all 20 million U.S. Veterans, is to focus our efforts on a comprehensive public health approach, known as Suicide Prevention 2.0 (SP 2.0). This approach combines community-based prevention and clinically based intervention strategies within every VA healthcare system. SP 2.0 is organized across three domains: universal, which encompasses all Veterans; selective, which targets those at an increased risk of suicide; and indicated, which is a smaller segment of those at a high risk. VHA's community-based prevention strategies address needs at state and local community levels. For state-level prevention, the Office of Mental Health and Suicide Prevention (OMHSP), in collaboration with our partners at the Substance Abuse and Mental Health Services Administration (SAMHSA), is supporting expanding the Governor's Challenges to Prevent Suicide Among Service Members, Veterans, and their Families, where state-level policymakers will partner with local leaders to implement a comprehensive suicide prevention plan, with a goal to invite all 50 states to participate by the end of FY22.

For local community action, OMHSP is supporting expansion across all VISNs of a Community Engagement and Partnerships – Suicide Prevention (CEP-SP) program focused on community

coalition-building coupled with targeted outreach and education, as well as the Together With Veterans (TWV) program, a VA Office of Rural Health program focused on empowering and supporting Veteran leadership for suicide prevention. These community-based interventions expand the capacity of VISNs to engage in community-based suicide prevention efforts in their region, thereby reducing population suicide rates among Veterans.

For the clinically-based strategy of SP 2.0, planning is currently underway, in partnership with VA's Clinical Resource Hubs (CRH), to develop and support the delivery via telehealth of evidenced-based interventions for suicide prevention, highlighted in the recently released VA/DoD Clinical Practice Guideline (CPG) on the Assessment and Management of Patients at Risk for Suicide (https://www.healthquality.va.gov/guidelines/MH/srb/). The initial focus will be on the roll out of Cognitive Behavioral Therapy for Suicide Prevention (CBT-SP) and will move to other therapies such as Problem-Solving Therapy for Suicide Prevention (PST-SP). The CPGs also advise the development of a crisis response plan, or safety planning intervention, for individuals with suicidal ideation and/or a history of suicide attempts. SP 2.0 will include promoting Advanced Safety Planning Intervention (ASPI) in Veterans with suicidal ideation and/or a history of suicide attempts.

SP 2.0 is informed by the evidence supporting suicide prevention interventions and public health approaches. The CDC, SAMHSA, and the National Action Alliance for Suicide have all moved toward a public health approach to suicide prevention. The model works to incorporate reaching both Veterans in the community as well as those we currently serve in the VA with innovative community-based prevention strategies combined with strategies with known outcomes for reducing suicide and suicide attempts based upon the recently updated VA-DoD CPGs.

We believe that the advancement of a public health approach to suicide prevention will save lives. These strategies are evidence-based and address gaps in existing VA suicide prevention programs, which have been primarily focused on internal strategies to reach Veterans within our system. By targeting both community prevention and clinical intervention, we improve our ability of reaching all 20 million U.S Veteran, not just those in VA care.

> *Question 5a.* How does VA decide which mental health/suicide prevention programs receive increases or decreases in funding?

Response: Mental Health Programs:

OMHSP outlines in policy which mental health and suicide prevention programs at a minimum must be available for Veterans at all VA Medical Centers. Funding for these programs is included in the overall budget established by VHA, which is broadly based upon historical and projected workload. VA Medical Center leadership makes local decisions on increases and decreases in funding mental health and suicide prevention programs.

OMHSP does receive office and special purpose budgets from VHA. Funding decisions for Mental Illness Research, Education and Clinical Centers (MIRECCs), Centers of Excellence (CoEs) including the National Center for PTSD (NCPTSD), targeted Suicide Prevention efforts,

and special purpose dollars allocations are made to address current priorities and programmatic goals.

In regard to specific mental health programming outlined in VHA policy, OMHSP's decisions regarding the programs comprising the VHA continuum of mental health care are informed by research (both historical and ongoing, innovations from MIRECCs/CoEs), best practice standards, and current Clinical Practice Guidelines (CPGs).

Suicide Prevention Programs:

Necessary increases in the budget request is multifactorial, but some of the main drivers include changes in the demographic in the VHA patient population, and major differences in propensity to use mental health services across demographics. Specifically, older white males are much less likely to use mental health services than younger, more female, and more racially diverse populations, likely due to shifting cultural norms around mental health care treatment and reductions in stigma associated with mental health treatment. VHA enrollees are becoming younger and more diverse over time, increasing demand for mental health services. Likewise, availability of telemental health services has increased functional accessibility of mental health service to Veterans who haven't used mental health services in the past. This is also expanding utilization of mental health services to a broader population of patients. The request for additional funding is largely in response to the projected increases in service demand estimated by VA models that take into account these trends in service utilization among VHA enrollees.

VHA provides VISN and facility leadership detailed information on projected growth in mental health care utilization over time with both near-term (next year) and long-term (next decades) horizons, so that they can plan expansions of mental health care in anticipation of this demand. However, use of actual funding is determined by local VISN and facility leadership based on their understanding of their local needs, and competing priorities.

The National Suicide Prevention Program within the Office of Mental Health and Suicide Prevention (OMHSP) works closely with our various Centers of Excellence and Program Evaluation Centers to review the ongoing performance and funding for operational support that is provided to sustain existing suicide prevention efforts, such as Recovery Engagement and Coordination for Health – Veterans Enhanced Treatment (REACH VET) REACH VET and Safety Planning in the Emergency Department (SPED). Quarterly reports are submitted for review and sustainment funding is reviewed annually. The same general process is also in place for the funding of field-based demonstration projects. Overall, we assess program and project funding requests to ensure that the scope, objectives, and intended impacts are in alignment with suicide prevention mission and goals and the National Strategy for Preventing Veteran Suicide and with the 2019 VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide.

Question 5b. What criteria does VA use to determine if programs are achieving their goals and benchmarks and are successful?

Response: VHA utilizes a broad array of both public sector and VHA-specific metrics to monitor mental health programming at the facility level. Public sector metrics include standard Healthcare Effectiveness Data and Information Set (HEDIS) and ORYX metrics. Specific public section mental health related metrics, however, are limited. VHA has created a broad array of metrics looking at access, utilization, satisfaction, and quality. The Office of Mental Health and Suicide Prevention monitors metric performance, provides quality improvement specialists for low performing sites, and conducts quarterly calls with VISN Chief Mental Health Officers to review challenged sites. OMHSP does not make direct budgetary decisions on facility funding based upon metric performance.

VHA Office of Mental Health and Suicide Prevention (OMHSP) Program Evaluation Centers have developed mental health management tools for performance improvement and program evaluation. For example, the VA Strategic Analytics for Improvement and Learning Value (SAIL) Model is used to measure, evaluate, and benchmark quality and efficiency at medical centers to promote high quality, safety, and value-based health care. SAIL assesses 25 Quality measures including specific metrics assessing mental health care. These metrics are reviewed and utilized for decision making and technical assistance to close gaps to offering the best care. These reports are publicly available on the VA Web site: https://www.va.gov/qualityofcare/measureup/strategic_analytics_for_improvement_and_learning_sail.asp.

In addition to SAIL, OMHSP Program Evaluation Centers have developed measurement strategies to track and measure impact associated with suicide prevention programs, priorities, activities, and efforts aligned with the National Strategy for Preventing Veteran Suicide 2018-2028 and the 2019 VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide. Specifically, metrics associated with the VA's suicide prevention priorities are regularly tracked to monitor trends and successful implementation to include VHA suicide risk mitigation, enhanced care delivery for Veterans at risk of suicide, education and training, and outreach and awareness interventions. OMHSP also works in collaboration with the VISN Chief Mental Health Officers to identify sites which may be facing difficulties in implementation and offer technical assistance and consultation support to assist in process improvement.

Question 6. How much funding has VA requested for alternative treatments for mental health?

Response: The VA budget for Comprehensive Addiction and Recovery Act Programs (CARA) includes a portion that is specific to Patient Centered Care. This annual funding of approximately $30M which began in FY17 is the only funding intended primarily for Complementary and Integrative Health that VA has requested.

Question 6a. Has VA evaluated the effectiveness of programs providing alternative treatments for mental health?

Response: As a preliminary point of clarification, we generally now use the terms "complementary" or "integrative" to describe this category of therapies rather than "alternative." This is to make completely clear that we do not endorse using these therapies to the exclusion of evidence-based conventional approaches, but rather in addition to and in support of these.[2]

Substantial progress has been made in building infrastructure to support increased access to Complementary and Integrative Health (CIH) services for Veterans as a part of their treatment plan. On May 19, 2017 VHA Directive 1137 was approved, establishing internal policy regarding the provision of CIH approaches. The current list of approved evidence based CIH approaches covered by the Veterans Medical Benefits package includes acupuncture, meditation, yoga, tai chi/qi gong, biofeedback, hypnosis, guided imagery, and massage as covered benefits if appropriate as part of the Veterans care plan. Chiropractic care was previously approved for use at VA in 2004 so was not included in this list but its use across the VA continues to increase.

Section 933 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) – Public Law 114-198 required demonstration projects on integrating the delivery of CIH services with other health care services provided by VA for Veterans with mental health conditions, chronic pain, and other chronic conditions. Rather than just adding these approaches into primary care, which may add to the burden, CIH approaches are delivered through a Whole Health System. Whole Health is an approach to health care that empowers and equips people to take charge of their health, well-being, and to live their life to the fullest, and is the primary delivery vehicle through which Veterans can access complementary and integrative health (CIH) services. The Whole Health System includes three components 1) The Pathway – empowers Veterans to explore mission, aspiration, and purpose and begin personal health planning; 2) Well-Being Programs equip Veterans with self-care tools, skill-building, and support. Services may include proactive CIH approaches such as yoga, tai chi, or mindfulness. 3) Whole Health Clinical Care – in the VA, community, or both, clinicians are trained in Whole Health and incorporate CIH approaches based on the Veterans personalized health plan. VA staff has been working with Veterans around the country to bring elements of this Whole Health approach to life. In conjunction with the CARA legislation, VA began implementation of the full Whole Health System in 18 Flagship Facilities in the beginning of FY 2018, the first wave of facilities in the national deployment of Whole Health. Flagship Facility implementation of the Whole Health System will proceed over a three-year period (FY 2018 - FY 2020) and is supported by a well-proven collaborative model which drives large scale organizational change. Preliminary evaluation data from the Flagship facilities demonstrated that since 2017, there was a 193% increase in utilization among Veterans with chronic pain, 211% increase among Veterans with mental health diagnoses, and 272% increase among Veterans with chronic conditions at these sites.[3] In addition, Whole Health

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[2] For the same reason, the National Center for Complementary and Alternative Medicine at NIH has now changed its name to "National Center for Complementary and Integrative Health."

[3] Bokhour BG, Hyde JK, Zeliadt S, Mohr DC. Whole Health System of Care Evaluation- A Progress Report on Outcomes of the WHS Pilot at 18 Flagship Sites. 2020. Veterans Health Administration, Center for Evaluating Patient-Centered Care in VA (EPCC-VA). Available at: https://www.va.gov/WHOLEHEALTH/professional-resources/clinician-tools/Evidence-Based-Research.asp

System service use among Veterans with mental health conditions was associated with smaller increases in outpatient pharmacy costs (3.5% annual increase) compared to similar Veterans who did not use WHS services (12.5% annual increase) at Flagship facilities.[2]

Section 932 of CARA required the development of a plan to expand research, in addition to education and delivery of CIH approaches.VA Office of Research and Development (ORD) has supported a comprehensive program of research that is focused on testing and implementing CIH approaches and has strengthened the evidence using CIH in diverse conditions such as chronic pain and Posttraumatic Stress Disorder (PTSD) using a variety of approaches. VA Research is committed to advancing the research on CIH for mental health conditions, as well as other chronic health issues. To date, CIH approaches for chronic pain management have been at the forefront, although mental health conditions have increasingly been on the CIH research agenda as well. In a collaboration with program offices responsible for the delivery of clinical care, ORD continues to refine this agenda and fund projects twice a year under a standing solicitation that identifies our interest in CIH and Whole Health as priority areas. VA is a member of the National Institutes of Health (NIH) - Department of Defense (DOD) - VA Pain Management Collaboratory (PMC). We expect projects developed from those collaborations to provide important data during the coming 2-3 years.

The VA Health Services Research & Development, Evidence Synthesis Program has published a series of reports to make high quality evidence synthesis available to clinicians, managers and policymakers as they work to improve the health and healthcare of Veterans. This includes various reports related to CIH, for a full list of published reports visit: https://www.hsrd.research.va.gov/publications/esp/reports.cfm

Additional VA CIH evaluation and research reports can be found here: https://www.va.gov/WHOLEHEALTH/professional-resources/clinician-tools/Evidence-Based-Research.asp

PEER program

Question 7. What amount of funding requested for the PEER program in the FY 2021 budget?

Response: The 2021 President's Budget included $5.6 million for the PEER program. The funding level is not specified in the PB and was supported with approximately $2M in FY20. Moving forward, the program is expected to be fully supported with approximately $5.6M in FY21 and again in FY22, based upon identified requirements by the Program Office.

Question 7a. What accounts does the PEER program funding come from?

Response: The PEER program is funded through the Medical Services account. Funds in support of the Peer Specialist program are from the Medical Services (0160) account.

Question 7b. How is the money for the PEER program allocated?

Response: Monies are allocated to the medical center for staffing support based on actual hires. Funds are distributed to the field based upon requirements identified by the Program Office.

Each facility projects its FTEE cost following onboarding of the peers and reimbursed accordingly.

Question 8. Why is VA seeking to modify the qualifications of PEER specialists?

Response: Section 405 of Public Law 110-387 directed VHA to establish the peer specialist position with the following criteria for eligibility: (A) be a Veteran who has recovered or is recovering from a mental health condition; and (B) be certified by either--(i) a not-for-profit entity engaged in peer specialist training as having met such criteria as the Secretary shall establish for a peer specialist position; or (ii) a State as having satisfied relevant State requirements for a peer specialist position. While the existing law has helped VHA establish the availability of peer support services for Veterans being treated in mental health and addiction treatment programs, the law prohibits VHA from hiring peer specialists in non-mental health programs that treat Veterans with physical health conditions (e.g., spinal cord injuries, amputations, traumatic brain injuries, or prolonged conditions like diabetes or chronic pain) where Veterans would also benefit from working with peer specialists who have found success with living with similar physical health challenges. If the qualifications for a peer specialist are permitted to be broadened in the way that VHA is requesting, it will allow VHA to hire peer specialists who have successfully addressed the physical health conditions that Veterans are being treated for in our inpatient and outpatient non-mental health programs. This will ensure that Veterans with physical health conditions will also be able to access and benefit from working with peer specialists who can assist the Veterans by inspiring hope through sharing part of their own experiences and helping the Veterans to advocate for themselves and connect to additional available supports and resources.

Question 8a. What will be the new qualifications to be hired as a PEER specialist?

Response: The proposed change is to modify the health conditions qualifications for peer specialists established in Public Law 110-387, Section 405, that added the position of "Peer Specialist" to U.S.C.§ 7402 - Qualifications of appointees. Section 7402(b)(13) of this title would be amended by replacing the existing section with:

(13) Peer Specialist. -- To be eligible to be appointed to a peer specialist position, a person must be a Veteran who has been trained as required by the Secretary and recovered or is recovering from a—

(A) mental health condition, if the individual is certified by--

(i) a not-for-profit entity engaged in peer specialist training as having met such criteria as the Secretary shall establish for a peer specialist position; or

(ii) a State as having satisfied relevant State requirements for a peer specialist position; or

(B) chronic physical health condition, disease or injury; and

(i) have completed training having met such criteria as the Secretary shall establish in order to demonstrate competence to deliver peer support services to Veterans with these medical conditions.

OAWP

Question 9. How much funding is requested for the Office of Accountability and Whistleblower Protection in the FY 2021 budget?

Response: For 2021, OAWP is requesting $26.4 million, which includes funding for 125 full-time equivalent employees (FTE). This is an additional $4.3 million over the budget proposed by the President in 2020 and includes funding for an additional 11 FTE. This increase will allow OAWP to implement the oversight and compliance requirements of the Act and continue to conduct thorough and timely investigations into whistleblower disclosures, allegations of senior leader misconduct and poor performance, and whistleblower retaliation.

Question 9a. How will this funding be allocated within the office? Please provide specific line items.

(Dollars in thousands)	2021 PB Request
FTE:	125
Central Office	57
Field	68
Funding:	
Personal Services	$20,228
Travel	$300
Transportation of Things	$10
Rents, Communications & Utilities	$400
Printing and Reproduction	$9
Contracts	$5,165
Tuition and Training	$250
Supplies and Materials	$60
Total	**$26,422**

Senator Hirono

Race and diversity

What is happening in our country right now is a tremendous acknowledgement of the disparities that have existed for so long. The pandemic has further exposed the disproportionate access people of color have to critical services like health care, housing, and social supports. Protests are happening all over the world – including in Hawaii – in response to violence against Black Americans. We're at a time in our country where we can't just go back to things as usual. I don't know what moving forward looks like, but we can no longer close our eyes. If ever there was a time to have some kind of reckoning, this is it.

Question 1. When the top leadership of our agencies does not reflect the people they serve, that can have real, lasting consequences. You are the leaders of the VA and you are all of one race. I'm not going to point fingers and assign blame, but I want to ask if you acknowledge that diversity is a good thing in order to provide truly equitable services to veterans who have given much to our country?

Response: The Department of Veterans Affairs (VA) is committed to promoting Equal Employment Opportunity (EEO), workforce diversity, and workplace inclusion. Since 2007, VA's top executive leader played a vital role in authorizing the supporting infrastructure. VA authored and executed a best in government Diversity and Inclusion Strategic Plan, one that was recognized and adopted by other federal agencies as a model plan. Our Technical Assistance Review Program incorporated visits to field facilities to measure their progress, assess their programs, and recommend improvements. Departmental goals and strategies that fostered consistency and results were key to our progress.

The Secretary of Veterans Affairs chartered the Diversity and Inclusion in VA Council (DIVAC). To ensure broad awareness of issues and to promote inclusive engagement, this senior executive-level council deliberates on diversity and inclusion matters throughout the year. These organizational representatives can verify that their individual organizations are implementing effective practices to continually transform their respective VA components. Additionally, the DIVAC serves as a strategic communication link between the workforce, sub-component organizations, and VA leadership, and as a clearinghouse on EEO, diversity, and inclusion matters.

Question 2. What are you doing as leaders of the VA to incorporate a more diverse set of voices and experiences into VA's decision-making?

Response: VA tracks on a continuous basis, the Department's efforts to attract, retain and develop a diverse leadership pool to support succession planning and talent management. The Department's long-standing Leadership VA (LVA) Program is open to all interested employees to apply for leadership development. The LVA Program develops their talent, skills, and

competencies essential for understanding and leading VA's mission. Eligibility for this program is limited to applicants GS-13 through GS-15.

In VHA, improving diversity and inclusion is a priority and is focused on ensuring the well-being of our Veterans, our employees, and the services we provide. As an organization, VHA embraces diversity and inclusion to foster innovation, increase job satisfaction and performance and ultimately improve the provision of care to our Veterans. This past year at the direction of Dr. Richard Stone, the Executive in Charge of Veterans Health Administration, and Dr. Steven Lieberman, the Acting Deputy Under Secretary for Health, VHA formed a Diversity & Inclusion (D&I) Modernization Team to recommend improvements to this program.

This team comprised a diverse group of staff at different levels of the organization, representing both the field and VA Central Office. This Team obtained input from industry leaders in the area of diversity and inclusion from both the healthcare industry (e.g., The Cleveland Clinic, University of Pennsylvania Perelman School of Medicine, Mount Sinai Icahn School of Medicine, The Centers for Medicare & Medicaid Services) and the non-health care industry (Google). Additionally, feedback was obtained from VA staff from a variety of backgrounds and at different levels of their careers during 13 listening sessions. Based upon these inputs, the Modernization team held a 3-day face to face sequester meeting that led to comprehensive recommendations for improvements.

A key recommendation was to expand and realign the D&I Office to report directly to the Acting Deputy Undersecretary for Health. The modernized D&I Office will focus on recruiting and retaining staff at all levels from entry-level and mid-level, to senior-level positions to ensure our workforce best reflects the nation's population and the Veterans we serve. This focus will include differing minority races and genders, those in our LGBT community, and persons with disabilities. The D&I Office Director will also chair the VHA Diversity Committee comprising field and Central Office representatives who are responsible for making actionable recommendations through the VHA Organizational Health Council to the VHA Governance Board to ensure that issues related to diversity, equity, and inclusion are an explicit part of the strategic oversight of VHA.

Question 3. Implicit bias is real and can have material and serious consequences on how we treat our fellow Americans. Can you please detail the efforts VA engages in to address implicit bias?

Response: On April 4-6, 2014, VA Office of Diversity and Inclusion arranged and offered an Unconscious Bias Training course for the purpose of initially educating VA professionals across the enterprise who routinely worked in functional areas related to EEO, diversity, inclusion, program quality management and human resources. The contractor, Cook Ross, provided instruction on the specific topic of unconscious bias by presenting proprietary material developed by this company. Participants were engaged for two days of didactic presentations, participant exercises, and participants teach-back sessions to enhance their instructor skills, knowledge of the content, and facilitation of the learners' experience.

By 2015, VA's Chief Diversity and Inclusion expanded research on the topic of bias when it was discovered that some of the Cook Ross proprietary material did not reflect current research on

the topic. VA conducted research to identify current and advanced research material. As a result, VA produced comprehensive learning material on implicit bias and its implications in workplaces with diverse teams, staff, or the workforce at large.

Formal course content was developed, and experienced instructors in the Office of Resolution Management, Diversity and Inclusion (ORMDI) conducted this training to staff VA-wide over the next six years upon request. Often the decision to conduct this course was based on formal training needs assessments, and the course remains one of the more highly requested courses in the ORMDI training program. Additionally, the course was delivered to participants in a leadership development program "Leadership VA" during the years 2017 through 2019.

ALOHA Project

For years, I have brought up the Advanced Leeward Outpatient Healthcare Access (ALOHA) Project in hearings and meetings with VA leadership. The ALOHA Project was scheduled to be completed by Fiscal Year 2020, but has encountered multiple delays. Earlier this year, VA said that a lease award was expected by mid-May, but in the recent weeks, we have learned that has been further delayed due to COVID-19. Now, a lease award is not expected until mid-August, and the project is not expected to be completed until spring 2023.

Question 4. Can you please explain what exactly is causing yet another delay, how VA is working to address it, provide a detailed timeline for the ALOHA Project, and commit that a lease award will occur no later than the end of August 2020?

Response: VA submitted the amended prospectus to the General Services Administration (GSA) and the Office of Management and Budget (OMB) at the same time on February 20th. OMB asked GSA to review the amended prospectus package; GSA cleared on March 3, 2020. OMB responded to VA on April 6, 2020, noting concerns on scoring. VA currently lacks sufficient maximum rent cap authority from Congress to award. Existing pricing results in a capital lease designation, which would preclude VA from making an award. VA has been working with GSA and OMB on this scoring issue to allow the amended prospectus to be submitted to GSA's Congressional Committees. The Committees will then need to pass a Committee Resolution, which will allow VA to take actions to make an award. While actual timing is dependent on Committee action, VA is hoping to make an award in the first quarter of FY 2021.

The of Construction and Facilities Management (CFM) believe they have a way forward that now just needs GSA to OK and to set up a final meeting w/ OMB. Informal discussions with GSA are very positive. We will meet with GSA next week to go over details and then meet with OMB (and GSA) to review for OMB's approval. With OMB's nod, GSA will send an amended prospectus to Senate EPW and House T&I committees

The way forward includes the potential shifting of some of what would be covered in the rent to an upfront payment (essentially for some health care-specific items). VA CFM still must complete the back-up work, including obtaining information from offerors. CFM is also working with VHA to ensure VA can fund a relatively small increase in the proposed upfront lump sum payment.

Homeless veterans during COVID-19

The COVID-19 crisis has once again highlighted the inadequate level of funding for federal homelessness programs, including those administered by VA. Homelessness in this country is an entirely solvable issue, and while we've seen a reduction in the number of homeless veterans in Hawaii and nationwide, we still haven't been willing to put our money where our mouth is and fund these programs at a level that would effectively end it. Now, we're dealing with a pandemic that has an outsized impact on those with preexisting health conditions, something we know is prevalent in all homeless communities, including homeless veterans.

Question 5. Is the FY20 funding request, along with the additional CARES Act funding, enough to ensure that VA is doing everything possible to keep veterans experiencing homelessness safe during COVID-19? And once we move beyond this pandemic, is there enough funding to make meaningful progress toward an end to veteran homelessness?

Response: Between the CARES Act and our 2021 President's Budget request, VA should have resources to meet the need. VA will continue to monitor and notify Congress should estimates change.

VA has also achieved impressive results in fighting Veteran homelessness by partnering with local governments, companies, and other stakeholders. In 2018, the total number of Veterans experiencing homelessness decreased 5.4 percent, and in 2019, that number dropped another 2.1 percent. In the last two fiscal years, VA has helped 124,900 Veterans and their families by providing housing or preventing them from becoming homeless. The success of these partnerships has led to 78 communities and three states effectively ending Veteran homelessness.

The 2021 President's Budget includes approximately $1.9 billion for homeless programs, $82 million above 2020. The 2021 request includes an increase of $30 million for case management for the U.S. Department of Housing and Urban Development-VA Supportive Housing (HUD-VASH) program. VA is committed to the objective of ending Veteran homelessness and pursues that objective in close collaboration with our Federal agency partners, leading national organizations, and State and local government agencies, and with VSOs and other nonprofit partners in communities across the country.

The VHA HPO has now received over $700M in CARES funding to support emergency housing placements, expanded residential capacity and services, and expanded homelessness prevention services in FY20 and FY21. That influx of funding, on top of the VHA HPO's existing budget, is sufficient to continue our broad and comprehensive response to homelessness during the COVID-19 crisis. We believe the funding we have received is sufficient to support SSVF program efforts supporting emergency housing placements, Housing and Urban Development – VA Supportive Housing (HUD-VASH) voucher holders, eviction prevention, and health care navigating, as well as Grant and Per Diem (GPD) and Health Care for Homeless Veterans Contract Residential Services (HCHV CRS) expanded services and placement options. The

most significant remaining question regarding funding will be if VA has sufficient funds to fully support homelessness prevention efforts. Given the large number of people who have lost their jobs, it is reasonable to expect a significant increase in the number of people at-risk for homelessness. We will continue to assess need in this area and will request additional CARES funding if the need exceeds our earlier estimates.

Campus-based veteran's resources

I have heard from colleges and universities in my state that additional campus-based resources to support student veterans would be helpful. Several of these institutions have benefited from VA programs like the Veterans Success on Campus Program ("VSOC"), which last year provided counseling services for more than 37,000 servicemembers, veterans, and dependents at 104 campuses nationwide. These institutions believe VSOC has been effective at promoting college completion and career success for students.

VA has indicated that it will "continue to hire and on-board additional VSOC counselors" to enhance its ability to serve more servicemembers, veterans and dependents:

Question 6. Can you elaborate on VA's work to enhance this program for student veterans and others?

Response: In July 2019, VBA implemented new VSOC performance standards that substantially require VSOC Counselors to conduct more in-person Chapter 36 counseling appointments. As a result, we have seen an increase in the amount of "professional counseling" contacts recorded in the VSOC database. VBA's ability to track and report on VSOC data will be accomplished in FY21 with the implementation of VR&E's new Case Management Solution that is currently under development.

Question 7. Does this work include expanding the program to provide counselors at additional campuses?

Response: VR&E currently maintains a waiting list of over 250 Institutions of Higher Learning (IHLs) who have requested a VSOC Counselor for their campus. It is VA's intent to expand this very successful program as new resources become available.

Question 8. Besides VSOC, what other campus-based programs have been effective for students?

Response: VSOC is VR&E's only campus-based program. There are no other campus-based programs under the purview of VR&E.

Access to telehealth

I have long advocated for expanded access to telehealth, which is particularly necessary for a rural and isolated state like Hawaii, and of increased importance during this COVID-19 pandemic as veterans must shelter in place.

Question 9. The CARES Act gave VA authority to partner with telecommunications providers to subsidize broadband services for veterans to ensure they have access to tele-mental health appointments, but I understand VA has not taken any steps to implement this new authority. Why is that?

Response: VA has taken actions in this critical area to improve Veterans access to internet, technology, and ultimately, to care:

- **ATLAS** – VA's Accessing Telehealth through Local Area Stations (ATLAS) initiative, in partnership with Phillips, Walmart, and Veteran Service Organization, intends to address the digital divide in rural and remote areas where fewer options for connectivity are available. At five Walmart locations and several Veteran Service Organizations, private rooms with telehealth equipment and high-speed internet have been established for Veterans to securely connect to their VA care teams by telehealth. While the ATLAS project was initially paused to ensure safety during the pandemic, the initial ATLAS locations are beginning to open with new infectious disease procedures.

- **iPad Program** – VA is taking strides to bridge the digital divide for individual Veterans who lack the technology or broadband internet connectivity required to participate in VA telehealth. More than 45,000 cellular-enabled tablets are currently distributed to Veterans across the country.

- **HUD-VASH Program** – VA is expanding its equipment loaner program to include iPhones for HUD-VASH Veterans. VA has procured these devices and is finalizing the process for dissemination to the field. Additionally, VA's is purchasing approximately 50,000 disposable smartphones with unlimited data plans for Veterans in VA Homeless Programs to ensure that Veterans remain connected with caregivers and supports, participate in telehealth, and have access to employment and housing resources. VA is currently expediting procurement and dissemination of the phones to VA Medical Center Homeless Program leads for distribution to Veterans engaged in the Homeless Programs.

- **Digital Divide Consult** – VA is accelerating the implementation of a national digital divide consult. This consult will be used when Veterans could benefit from connected care technologies but are identified as lacking access to the technology or internet connection necessary to participate. Through this consult, VA intends to help Veterans leverage benefits available through VA, other federal agencies, and the private sector to help Veterans connect remotely with VA services. The VA initiatives that will be initially available through the digital divide consult include the connected iPad program

and a new connected phone pilot program for HUD-VASH Veterans. Through the consult, Veterans will also be assessed for eligibility for the FCC's LifeLine program which can subsidize a Veterans internet or phone service.

- **Additional Partnerships:** VA has contacted Internet Service Provider representatives that were provided by Congress to obtain new ideas, services and agreements that can assists with obtaining broadband services for isolated Veterans. VA is also seeking additional private sector partners to help support Veteran access to internet services. An RFI was recently released to garner input and ideas. VA has previously established successful partnerships with several private sector companies for this purpose including with Microsoft, Verizon, T-Mobile, SafeLink by Tracfone, and Sprint (now owned by T-Mobile) and will be announcing additional partnerships soon. Through the RFI, VA intends to find additional partners ready to support Veteran's access to telehealth services.

Question 10. Does the VA have any estimate of how many veterans lack access to broadband services?

Response: Based on an FCC report from 2019, about 2.2 million Veteran households lack either fixed or mobile broadband connections at home. An internal project with Microsoft Airband, using FCC and VA data, showed that about 137K (137,397) Veterans live greater than 60 minutes away from a VA facility without access to 10/1 internet speed with almost 300,000 (294,008) living greater than 60 minutes from a VA facility without access to broadband internet (25/3) speeds.

Question 11. As VA begins to reopen, many veterans – especially those at higher risk for COVID-19 – may still feel uncomfortable going to a doctor's office and may prefer to use telehealth? How will VA continue to support enhanced access to telehealth? Do you need additional resources to meet this need?

Response: VHA wants Veterans to have options for how they receive their health care. Our goal is to make sure that Telehealth is one of those options when preferred by the Veteran and medically appropriate. VHA continues to review and analyze the exponential growth of telehealth services precipitated by the COVID-19 Pandemic to compile lessons-learned from providers, Veterans and their care givers' experiences to forecast future needs in alignment with Veterans preferences and VA strategic plans.

VHA believes its FY21 telehealth budget request is sufficient based on current plans with one potential exception. The equipment needed to support Veterans access to technology and internet services, such as iPads, iPhones and related equipment items, will exceed initial projections if the COVID-19 Pandemic continues to surge.

Cuts to Medicaid

The President's FY21 Budget includes $500 billion in cuts to Medicaid. Nearly 1 in 10 veterans receive some health care coverage from Medicaid. Slashing Medicaid, as the president has proposed, could increase reliance on and demand for care at the VA. The VA budget request does not address how these harmful Medicaid cuts could limit access to care for veterans, and increase spending at the VA.

Question 12. Has the VA estimated how huge cuts to Medicaid would impact access to health care for veterans and demand for services at the VA? If so, what have you found? And if not, do you think it is important to understand how veterans would be impacted by these cuts?

Response: Prior to the start of the COVID pandemic, approximately 12% of VHA enrollees under age 65 were also eligible for Medicaid, including approximately 3% that were eligible for both Medicare and Medicaid in addition to VHA. The Medicaid eligible percentage has likely increased through the pandemic as the recession has led to loss of income and employment-related health care coverage for some enrollees.

If a work requirement were imposed under state Medicaid programs or if federal funding for Medicaid were reduced, this could lead to loss of Medicaid coverage for some enrollees. Enrollees who lose sources of non-VHA health care coverage are expected to increase their reliance on VHA for their healthcare needs. The work requirement is intended to apply to those who are able-bodied, and less likely to suffer from significant, multiple medical conditions and disabilities. Therefore, the expenditure impact of increasing their reliance could be less than for other groups of Medicaid beneficiaries who have more illness and disability. Those enrollees under age 65 also eligible for Medicare typically have severe disabilities and are unlikely to lose Medicaid coverage.

Other proposed Medicaid reforms in the president's budget could have an impact on VHA expenditures. For example, the emphasis on mental health and substance abuse treatment may improve health outcomes for Medicaid beneficiaries who are also enrolled with VHA, and this could reduce VHA expenditures on healthcare that is directly or indirectly related to mental health and substance abuse disorders.

GI Bill Access to Career Credentials Act

Last year I worked with Senator Rounds to introduce legislation to make it easier for veterans to become licensed or certified in their chosen careers. Specifically, we introduced the GI Bill Access to Career Credentials Act (S. 2345), which allows veterans to use their GI Bill educational benefits to pay for approved courses that prepare them for career licensure and certification exams. The bill also has bipartisan support in the House.

I was glad to see this proposal included in VA's budget for FY2021:

Question 13. Given that today's veterans are more diverse than ever before when it comes to their education and career pathways, can you elaborate on why this proposal would be helpful for veterans?

Response: This proposal would be helpful for Veterans and other educational beneficiaries by allowing them to receive reimbursement for the cost of a preparatory course for a test that is required or used to enter into, maintain, or advance in their given vocation or profession. Currently, VA educational assistance can be paid to reimburse the costs of fees associated with licensing and certification exams that are required to enter into, maintain, or advance in a given vocation or profession (e.g., state bar exams, medical board exams, electrician exams, Microsoft® certifications, etc.). However, benefits cannot be paid for the costs of classes designed to prepare individuals to take exams. This stands in stark contrast with tests for admission to an IHL (e.g., SAT, ACT, GRE, LSAT, etc.) for which VA educational assistance can be paid for both preparatory courses and reimbursement of test fees.

Question 14. What are the benefits of allowing veterans to use their educational benefits to prepare for career licensure and certification exams?

Response: Allowing Veterans to use their educational benefits to prepare for career licensure and certification exams would increase their chances of successfully obtaining a license or certification and, thus, have a positive impact on their overall employment prospects and economic success.

Questions 15. What other proposals would be helpful for veterans?

Response: The following legislative proposals, as shown in VA's FY 21 Budget Submission, would be helpful for Veterans:

Authorization of VA to Approve Interstate Commerce Carrier Apprenticeship Programs
This proposal would authorize the Secretary of VA to approve apprenticeship programs operated by interstate commerce carriers that operate in more than one state. This proposal would restore authority VA previously had that was unintentionally eliminated by Public Law 115-89.

Eliminate the Requirement to Submit a Signed Training Agreement for On-The-Job Training Programs
This proposal would eliminate the requirement for a training facility to submit a signed training agreement to VA for on-the-job training and apprenticeship programs. The current requirement often delays claims processing since VA is prohibited from processing an on-the-job training claim until the training agreement is received. VA instead proposes that the training agreement be kept on file at the training facility.

Require an Individual to Make an Election to Receive Educational Assistance Under MGIB-AD (Chapter 30)
This proposal would require an individual to make an election to receive MGIB-AD educational assistance before the Department of Defense (DoD) can begin the $100 pay reduction. VA

believes it is no longer beneficial to require individuals to decline the MGIB-AD program. Rather, individuals should be required to "opt-in" to the program before their pay is reduced. MGIB-AD benefits pay significantly less, and the number of beneficiaries has decreased since the inception of the Post-9/11 GI Bill.

Prevent VA from Providing Unlimited Amounts of Payment for Flight Training at Public Schools
This proposal would impose tuition and fee payment caps at institutions of higher learning (IHL) with flight training programs and establish a maximum allowable fee structure for all VA-funded flight programs. This recommendation would eliminate specific targeting of Veteran students for enrollment in these programs and would promote greater consistency in program administration.

Intimate partner violence

Experts are concerned that stay-at-home orders across the country will cause intimate partner violence to increase. Women veterans are particularly susceptible to experience intimate partner violence.

Question 16. Is the VA conducting any proactive outreach to women veterans in response to COVID-19 stay-at-home orders to make them aware of VA's resources for victims of intimate partner violence?

Response: The VA Intimate Partner Violence Assistance Program (IPVAP) provides clinical and support services to promote the relationship health and safety of Women Veterans, including those susceptible to experiencing intimate partner violence (IPV) during the COVID-19 stay-at-home orders. IPVAP Coordinators at VA facilities provide screening, assessment, safety planning and intervention for Veterans and their intimate partners. VA Staff conduct IPV screening for Veterans via telephone or Video Telehealth modalities and were trained to assess for risk before engaging in IPV screening or discussion. VA staff utilize safe strategies for communication with Veterans through telephone and virtual technologies, including asking yes/no questions to assess environmental factors and safety prior to discussing relationship health and safety (e.g. asking are you alone, which can be responded to with a simple "yes" or head nod, if on video). VA is working to ensure that Veterans, their partners, and VA staff are well informed of IPV risk and have current information on resources and supports available. Resources are shared through VA social media platforms, internal emails, posting flyers and other materials, and working directly with Veterans to ensure individual safety is addressed.

VA Medical Centers are partnering with external stakeholder organizations with similar practices for reducing IPV risk. For example, VA established a Memorandum of Understanding (MOU) with the National Domestic Violence Hotline (NDVH). Through this MOU, all Veterans can access support 24 hours a day, 7 days per week via phone, text, or web. NDVH has access to a listing of VA IPVAP Coordinators from each medical center to provide locality-specific VA contact information to callers. The IPVAP public-facing website maintains an informative and interactive content and offers a roster of VA Medical Center IPVAP contacts by state. In order to reduce risk associated with accessing IPV-related content online (e.g., if a partner walked into

the room or accessed web history), the IPVAP website offers a "quick escape" button which redirects to the va.gov page.

Senator Manchin

Question 1. As you know, I introduced a bill with my colleagues to require the VA Crisis Line and National Suicide Hotline to have a 3-digit dialing code for Veterans to quickly gain access to lifesaving mental health support. Once approved, how quickly can you implement a 3-digit dialing code for the Veterans Crisis Line? What other support will you need to get this done?

Response: The VA is in support of the 988-expansion initiative, a new national three-digit emergency telephone number to access crisis call centers across the country for suicide prevention and mental health services. As significant planning and staffing increases are necessary to handle the increased demand associated with the implementation of 988, the Veterans Crisis Line is prepared for a target activation date of July 16, 2022, as set forth by the FCC. We appreciate the current timeline to allow for hiring, training, and overall planning, which will be critical for appropriate implementation.

- Secretary Wilkie, one issue my staff and I have been hearing from Veterans is the length of time the VA takes to process non-service connection pension and Aid and Attendance claims for veterans and widows. Aid & Attendance provides help to Veterans and caregivers who are in nursing homes or who need in home care help with everyday tasks like dressing or bathing. Obviously, these benefits have become even more important in light of the coronavirus and its impact on the elderly. We have received responses that these claims can't be expedited due to advanced age unless the claimant is over 90. Because these are income based claims, it seems they should be able to be processed more quickly than service connected claims, especially with the VA cross referencing income with the Social Security Administration and the IRS.

Question 2. What can the VA do or what legislative support will you need from us to expedite Aid & Attendance claims for Veterans who may not be 90 years or older, but clearly need immediate assistance?

Response: VA's pension program is a needs-based program intended to provide a minimal level of financial security to recipients. Typically, the annual income for claimants attempting to qualify for pension benefits will be near or below the poverty threshold. VA considers all pension claims, including those applying for Aid and Attendance (A&A) benefits under the pension program, to be an indication that the claimant is experiencing hardship.

Regarding VBA's expedited processing criteria, written policy provides priority processing for pension claimants identified as meeting one of the following criteria: homeless, terminally ill, former prisoner of war (FPOW), Purple Heart recipients (original claims), and Medal of Honor recipients. For the purpose of pension claims only, VA does not automatically prioritize the processing of pension claims where the claimant is over age 85 or experiencing hardship because most of the pension workload meets these criteria. VBA's priority processing criteria does not limit the ability of VBA Regional Offices (RO) to expedite claims as requested, on a case-by-case basis.

VA is committed to ensuring that Veterans and survivors who are entitled to pension benefits based on the need for A&A receive them in a timely manner. VBA continues to collaborate with the VA Office of Information Technology in one of the largest automation efforts in the Department. This modernization effort will introduce automation to the pension program and will include the automation of original

Veteran and survivor pension claims, including A&A benefits. This modernization effort will drastically improve the timeliness of benefits delivery while maintaining high levels of accuracy.

In order to ensure effective implementation of Improper Payment Elimination Recovery Act (IPERA), VA utilizes federal tax information (FTI) to validate a pension claimant's income prior to the granting of benefits. To further improve pension benefits delivery, your support of the legislative proposal on FTI that is in VA's FY2020 Congressional Budget submission would allow VA to utilize more modern claims processing systems and expand automation of pension claims processes. Currently, VA must wait up to 16 days to begin processing original pension claims as it awaits the FTI data from the Internal Revenue Service and Social Security Administration. This change in the FTI law would also allow VA to pursue a direct data transfer of FTI data, which would eliminate the current delay in processing created by the need to wait for this data.

Senator Sinema

Question 1. Revisiting the question I asked regarding the need for VA to lead a national strategy to support homeless veterans during the coronavirus pandemic, I appreciated your answer outlining all of the programs that VA offers to assist homeless veterans and expansions of those efforts since the coronavirus pandemic began. However, there is no coordinate national strategy to support the homeless veteran population. These efforts are largely being organized at the local level, leaving local organizations to should much of the burden without the support of VA. A coordinated plan would outline interventions at the regional and local level, but would be coordinated across VA and its partners serving the homeless veteran community and should be created in collaboration with those partners. This would include a national testing strategy that addresses transportation to and from testing sites and/or mobile testing centers, provisions for housing and care for those who test positive, and support to partner organizations to keep their employees safe. What does VA need to create a national strategy to support homeless veterans during the coronavirus pandemic and why haven't you created and implemented this strategy thus far?

Response: The VHA Homeless Program Office (HPO) has developed and executed a coordinated national strategy to support homeless Veterans in response to the pandemic. The strategy continues to evolve based on emerging science about the disease and the needs of communities to support homeless Veterans during the crisis. Since March 2020, the HPO's strategy has consisted of:

Removing programmatic and policy barriers that impact VA-funded programs to immediately respond to the pandemic.

In immediate response to the COVID-19 crisis, the HPO issued formal guidance waiving programmatic requirements that could serve as obstacles to emergency responses to the crisis (e.g., time limits on hotel stays, Grant and Per-Diem (GPD) and Health Care for Homeless Veterans Contract Residential Services (HCHV CRS) facility inspection requirements); issued formal guidance to VA-funded grant and contract programs to support social distancing and options for isolation and quarantine; and issued formal guidance that provides guidance on Housing and Urban Development – VA Supportive Housing (HUD-VASH) admissions during the COVID-19 emergency, encouraging targeting of HUD-VASH vouchers to all eligible homeless Veterans who could benefit from a voucher.

In addition to establishing and clarifying policy, the HPO has worked with Congress to develop legislation in response to the pandemic. HPO has conducted seven formal briefings with the Senate and House Veterans Affairs Committees regarding VA's pandemic response; provided written replies to over 20 Requests for Information from Congress; and provided technical assistance to SVAC and HVAC by phone and in writing on draft provisions related to statutory flexibility needed to maximize VA's emergency response.

Rapidly increasing emergency housing and eviction prevention efforts by dramatically expanding services and funding through authorities granted by the CARES Act.

Since the passage of the CARES Act, $700 million in VA funding has been allocated to support homeless Veterans during the crisis to ensure that communities do not shoulder the burden of the response. $601.5 million has been allocated to the Supportive Services for Veteran Families

(SSVF) program to provide emergency housing and homelessness prevention assistance to mitigate the expected wave of evictions and potential homelessness that will result from extensive unemployment. Between March 17, 2020 and June 26, 2020 alone, 8,925 homeless Veterans have been placed in hotels/motels to facilitate social distancing measures by removing them from congregate and unsheltered settings. These funds also assist the HUD-VASH program by placing Veterans in safe housing to isolate them from the virus while they await their housing voucher. In addition, the SSVF program has funded SSVF healthcare navigators to increase access to both VHA and community healthcare services for Veterans in the SSVF program.

$88 million has been allocated to the GPD program and VA has waived per diem limits during the crisis to empower GPD grantees to provide necessary emergency housing and supportive services for Veterans who need to be isolated for their safety or the safety of others. As of July 17, 2020, GPD has approved 420 per diem rate increase requests tied to 8,989 transitional housing beds and seven service centers. This funding provides the needed resources to create additional temporary space to support social distance; provides additional funding for regular deep cleaning of facilities and purchase of personal protective equipment (PPE) for grantee staff; and provides funding to hire additional staffing resources to support.

$10 million has been allocated to the HCHV CRS program to provide emergency shelter and supportive services during the crisis, including placement in hotel rooms for Veterans needing emergency placement or isolation to avoid spreading the virus. Housing is paired with care, treatment, and rehabilitative services.

Guiding non-profit grantees and contractors by developing and executing a comprehensive technical assistance plan for community providers and VA medical center homeless program staff.

Recognizing the need for a coordinated national technical assistance strategy, in order to not leave local organizations and communities to shoulder the responsibility for the response, a comprehensive technical assistance plan has been developed and executed by the Homeless Program Office. This plan's execution has involved VA and community leaders at the national, regional, and local levels. The plan includes:

- *Development and execution of an internal communications and technical assistance strategy to ensure VAMC and VISN leadership have the most current information about HPO's coordinated strategy.*

This strategy includes the formation of a centralized response team that communicates with VAMC and VISN leadership daily and reviews inquiries from field staff and partner offices, confers with program subject matter experts, and develops and disseminates vetted guidance. HPO's response team has received and/or issued over 1,800 digital communications related to COVID-19 policies, technical assistance, and requests for assistance since mid-March 2020. In addition, the response team holds weekly calls with VISN Homeless Coordinators to provide the most updated information about the strategy and response and solicits field-level perspective so that adjustments can be made to HPO's coordinated response.

- *Development and execution of an external technical assistance strategy to ensure community partners have the most updated guidance related to the Federal coordinated response.*

SSVF has provided extensive technical assistance to 271 grantees located through the United States and its territories. This technical assistance has integrated novel approaches that has allowed SSVF to quickly adapt its service delivery model to meet the urgent needs created by the COVID-19 public health emergency. Close collaboration with local Continuums of Care, public health authorities, and VAMCs have supported extensive hotel/motel placements as an alternative for vulnerable homeless Veterans in congregate shelters, encampments, or the streets. SSVF Regional Coordinators and VA's Office of Business Oversight provide additional guidance and oversight for grantees on how to adapt their practices to meet current needs. Together, these staff work to ensure that CARES funding advances VA's mission to end homelessness among Veterans.

The GPD program office has provided technical assistance to all GPD grantees by hosting webinars as part their monthly call series with grantees. The webinars cover topics related to the COVID-19 response, and opportunities to utilize the flexibilities and funding associated with the CARES Act. In addition, the GPD program office has developed a variety of technical assistance products and provides links to CDC guidance which has been posted on the GPD provider website to assist grantees. The GPD office has also been participating in a series of conference calls with VISN Homeless Coordinators and VA GPD liaisons, providing consultation related to work with grantees to mitigate risks associated with COVID-19. GPD continues to work with grantees and VA staff daily.

The HCHV CRS program has supported contract providers by providing on-going technical assistance to the VAMC liaisons that work with HCHV CRS providers on a regular basis. This technical assistance has been accomplished through several means, including national calls and webinars, covering topics related to HPO's coordinated response. The HCHV program office continues to work with VISN and VAMC level staff daily. This includes, but is not limited to, individual calls with HCHV CRS programs who are considered high risk due to physical layout of their facility or other factors; to problem-solve COVID-related vulnerabilities such as cleaning protocols; wellness checks and isolation options; and to assist community providers with developing plans to increase safety measures within the given contracted program.

In addition to program-specific technical assistance our technical assistance strategy has included presenting on numerous national webinars, including Housing and Urban Development (HUD) weekly COVID-19 Office Hours and the National Health Care for the Homeless Council COVID-19 webinars since the start of the pandemic to present the national strategy with community providers and to provide guidance and technical support.

The HPO is closely coordinating with the VA Office of Public and Intergovernmental Affairs (OPIA) to develop strategies for expanding awareness of VA resources among Veterans who are homeless and at risk of homelessness during this public health emergency. Our goal is to reach all Veterans facing housing crises, including those who have never sought assistance from any safety net programs administered by VA or any other organizations. HPO and OPIA have identified three objectives to accomplish this goal:

- Serve as an information resource for Veterans, homeless service providers, partners, and the general public.
- Highlight the work underway by HPO personnel to support Veterans who are at risk of or experiencing homelessness.
- Connect with organizations that can fill needs gaps created or exacerbated by COVID-19.

Since implementation, numerous podcasts, blog posts, national news releases, and press interviews have been developed or have taken place. In addition, on July 9, 2020, the National Director of Clinical Operations participated in a satellite media tour with 20 local news outlets and one national news outlet, reaching up to 5 million audience members, to provide the public with awareness of the risk of COVID-19 for homeless Veterans and VA's response to support Veterans during this time.

Developing a plan for universal testing of Veterans in VA-funded congregate living environments.

The VHA HPO supports proactive testing of Veterans residing in congregate settings for early identification of COVID-19 cases and to aid in mitigating disease outbreaks in these high-risk locations. HPO has developed a policy memo and SOP document for universal testing in all GPD and HCHV CRS programs that is currently under review by VHA leadership.

An Assistant Under Secretary for Health for Operations memo and corresponding SOP regarding HPO's proposed SARS-CoV-2 universal testing protocol for Veterans in GPD and HCHV CRS programs has been developed and is currently under review. The testing memo and SOP provides the requirement that VAMC identify a COVID-19 testing team to conduct testing prior to program admission and on an ongoing basis for Veterans currently enrolled in GPD and HCHV CRS and are eligible for VHA care. The COVID-19 testing team must consist of at minimum one VHA provider for ordering of the test and provision of follow-up care. Additional recommendations in the proposed memo and SOP include the following: 1) coordinate testing events on site using the COVID-19 testing teams, rather than transporting Veterans to local VAMCs, to reduce the chance of disease transmission and increase access, 2) conduct testing events on weekends rather than weekdays to enhance access to testing for Veterans who may lack transportation or work primarily during the weekdays, and 3) include staff from Homeless Patient Aligned Care Teams (H-PACT) for COVID-19 testing teams when possible.

Ensuring there is a coordinated federal response by developing this plan with both internal VA offices and external federal partners.

Since the start of the crisis, the VHA HPO has worked closely with partner offices within VA (e.g., General Counsel, Information Technology, Connected Care and Telehealth, Mental Health, Geriatrics and Extended Care, Office of Emergency Management,) and across Federal agencies (Housing and Urban Development, United States Interagency Council on Homelessness, Centers for Disease Control, Health and Human Services) to provide a coordinated response and consolidated guidance to VA staff, grantees, contractors, and community partners serving homeless and at-risk Veterans. Staff from the Homeless Program Office regularly attend coordination meetings with CDC, U.S. Interagency Council on Homelessness (USICH) and other

federal partners to support drafting of policy and guidance related to care of homeless individuals and families during the crisis.

Expanding our ability to provide virtual care to homeless Veterans by securing resources to provide needed technologies.

The VHA HPO continues to work with multiple VA program offices, VAMCs and VISNs to identify barriers related to provision of telehealth services to homeless Veterans. The HPO identified that a key barrier related to provision of telehealth services to this population is the lack of access to telehealth technology for both VA homeless program staff and Veterans. As VA homeless programs rapidly mobilize resources and strategies to move Veterans into independent, permanent housing and hotels/motels to promote physical distancing, technology is vital to prevent these vulnerable Veterans from becoming socially isolated, which may trigger or exacerbate mental health symptoms. Technology also provides a mechanism to ensure that Veterans remain engaged with homeless program providers to monitor safety and wellbeing, participate in preventative healthcare, attend virtual groups and recovery programs, and conduct virtual housing and job searches.

Recognizing the need for these technologies, HPO is increasing capacity in its homeless programs by expanding telehealth and telecommunications capabilities. The CARES Act specifically requires VA to ensure that telehealth capabilities are available during a public health emergency for case managers of, and homeless Veterans participating in, HUD-VASH. In response to this requirement, the VA's Office of Connected Care (OCC) developed a process to ensure that HUD-VASH case management team members have the equipment necessary to provide telehealth services. An initial assessment of provider equipment needs resulted in procurement of approximately 600 iPads and more than 20,00 additional pieces of telehealth technology equipment (webcams, speakers, monitors, and headsets) which are currently in the process of distribution to the field. Additionally, OCC has expanded their equipment loaner program to include iPhones for HUD-VASH Veterans. They have procured these devices and are developing a process for dissemination to the field.

Additionally, at the end of April 2020, the VHA HPO obtained authority to purchase smartphones and data plans using appropriated funds for Veterans, and in June 2020, received $17M in CARES Act funding to purchase approximately 50,000 disposable smartphones with unlimited data plans for Veterans in VA homeless programs to ensure that Veterans remain connected with caregivers and supports, participate in telehealth, and have access to employment and housing resources. HPO is currently expediting procurement and dissemination of the phones to VAMC homeless program leads for distribution to Veterans engaged in homeless programs. The next steps are pending solicitation of a contract and Office of General Council (OGC) approval, due to the dollar amount. HPO also received a 600,000 Amazon donation prior to the CARES Act funding approval and worked with the Office of Procurement, Logistics, and Acquisition (OPLA) to sole source a contract and disseminate 1200 phones to homeless program leads at VAMCs in following cities: Boston, Philly, Battle Creek, Palo Alto, Las Vegas, and Kansas City. These phones arrived on or around July 22, 2020 and were immediately disseminated to Veterans in need by local homeless program leads.

Therefore, this multipronged approach demonstrates a thorough and comprehensive strategy, wherein VA has provided guidance, resources, and assistance to both internal VA medical center staff and external community partners. As VA learns more about the pandemic, and impact on

homeless Veterans, this plan will continue to adapt, and VA will continue to be flexible in our response.

Question 2. The veteran serving community in Arizona is concerned with the lack of guidance for adjudicating claims for Dependency and Indemnity Compensation (DIC) benefits in cases in which the sole cause of death listed on a veteran's death certificate is COVID-19. For veterans with certain service-connected illnesses, it's important that these be reviewed to determine whether the service- connected illnesses were contributory to their deaths. Claims adjudicators can make the decision to request a second medical examination or opinion in such cases if they feel it is warranted, but this can add time to the process and undue burden to the surviving family member. Will VBA release clear guidance outlining how DIC benefits should be processed for veterans whose death certificates list COVID-19 as the sole cause of death and to include a provision to automatically require a second medical examination or opinion to better expedite the process?

Response: VA is committed to providing timely service without unnecessary burden for survivors. VA's existing guidance in 38 CFR § 3.312 provides instructions on processing claims for service-connected death by considering the primary and contributory cause(s) of death along with the Veteran's service-connected condition(s). Existing guidance also addresses VA's duty to assist and when to request a medical opinion. If the claim cannot be otherwise granted and there is an indication that at least one of the Veteran's service-connected disabilities may be related to the principal or contributory cause of death, a medical opinion would be requested.

In response to the COVID-19 pandemic, VA issued a specific reminder to claims processors on April 23, 2020 regarding the processing of service-connected death claims. The guidance reinforced that claims processors must review all facts and circumstances surrounding the death of the Veteran to determine if there is a reasonable probability of service-connected death. The guidance explained that the complete clinical picture of COVID-19 is not fully known and people with serious underlying medical conditions seem to be at higher risk for developing severe COVID-19 illness. The guidance also reinforced VA's duty to assist when service connection for the cause of the Veteran's death cannot be granted based on the evidence of record.

VA does not believe the inclusion of a provision requiring medical opinions for any DIC claim where COVID-19 is listed as the sole cause of death is necessary or advisable. VA's duty to assist claimants under current law provides that the Secretary is not required to provide assistance to a claimant if no reasonable possibility exists that such assistance would aid in substantiating the claimant, see 38 U.S.C. § 5103A(a). For example, VA would not view a medical opinion as necessary or required if a surviving spouse filed for service-connected death benefits based on a COVID-19-related death and the Veteran, at the time of death, had a single service-connected condition of right ankle sprain at 0% disabling. Providing medical opinions in all cases would not represent a fiscally responsible policy.

Existing VA guidance also outlines scenarios where a medical opinion is not necessary to grant DIC benefits. If reasonable probability of service-connected death is found based on at least one of the following conditions, DIC can be granted without a medical opinion:

- service connection was granted for a condition affecting any vital organ
- the Veteran was rated 100 percent for a service-connected disease or disability, or
- the Veteran was entitled to individual unemployability.

DIC may also be paid in the same manner, as if the death were service-connected (without a medical opinion), if a Veteran was in receipt of, or entitled to receive, disability compensation for a service-connected disability which was totally disabling for:

- 10 or more years immediately preceding death
- a continuous period of not less than five years from the time of separation from service until death, or
- 1 or more years immediately preceding death if the Veteran was a former prisoner of war.

Question 3. Tribes across the country have been hit particularly hard by the coronavirus. Telehealth provides an opportunity to ensure quality health care to patients in rural communities. The CARES Act provided VA with authority to partner with telecommunications providers to subsidize fixed or mobile broadband services, an important step in delivering telehealth to those who need it. Yet, seven in ten residents on rural tribal lands do not have access to fixed high-capacity broadband. How will the VA ensure veterans in tribal communities have the broadband they need to access telehealth services?

Response: VA has taken actions to bridge the digital divide for Veterans in rural and highly areas, to include those residing in tribal communities but acknowledges it cannot overcome the digital divide for all Veterans alone:

- **ATLAS** – VA's Accessing Telehealth through Local Area Stations (ATLAS) initiative, in partnership with Phillips, Walmart, and Veteran Service Organization, intends to address the digital divide in rural and remote areas where fewer options for connectivity are available. At five Walmart locations and several Veteran Service Organizations, private rooms with telehealth equipment and high-speed internet have been established for Veterans to securely connect to their VA care teams by telehealth. While the ATLAS project was initially paused to ensure safety during the pandemic, the initial ATLAS locations are beginning to open with new infectious disease procedures. Assuming success of the program, the VA intends to expand ATLAS to additional areas of need.

- **iPad Program** – VA is taking strides to bridge the digital divide for individual Veterans who lack the technology or broadband internet connectivity required to participate in VA telehealth. More than 45,000 cellular-enabled tablets are currently distributed to Veterans across the country.

- **HUD-VASH Program** – VA is expanding its equipment loaner program to include iPhones for HUD-VASH Veterans. VA has procured these devices and is finalizing the process for dissemination to the field. Additionally, VA's is purchasing approximately

50,000 disposable smartphones with unlimited data plans for Veterans in VA Homeless Programs to ensure that Veterans remain connected with caregivers and supports, participate in telehealth, and have access to employment and housing resources. VA is currently expediting procurement and dissemination of the phones to VA Medical Center Homeless Program leads for distribution to Veterans engaged in the Homeless Programs.

- **Digital Divide Consult** – VA is accelerating the implementation of a national digital divide consult. This consult will be used when Veterans could benefit from connected care technologies but are identified as lacking access to the technology or internet connection necessary to participate. Through this consult, VA intends to help Veterans leverage benefits available through VA, other federal agencies, and the private sector to help Veterans connect remotely with VA services. The VA initiatives that will be initially available through the digital divide consult include the connected iPad program and a new connected phone pilot program for HUD-VASH Veterans. Through the consult, Veterans will also be assessed for eligibility for the FCC's LifeLine program which can subsidize a Veterans internet or phone service. LifeLine offers a monthly benefit of up to $9.25 towards phone or internet services for eligible subscribers (up to $34.25 for those living on Tribal/Native lands).
- **Additional Partnerships:** VA has contacted Internet Service Provider representatives that were provided by Congress to obtain new ideas, services and agreements that can assists with obtaining broadband services for isolated Veterans. VA is also seeking additional private sector partners to help support Veteran access to internet services. An RFI was recently released to garner input and ideas. VA has previously established successful partnerships with several private sector companies for this purpose including with Microsoft, Verizon, T-Mobile, SafeLink by Tracfone, and Sprint (now owned by T-Mobile) and will be announcing additional partnerships soon. Through the RFI, VA intends to find additional partners ready to support Veteran's access to telehealth services.

Question 4. As VA returns to pre-COVID-19 operations, I'm concerned that increasing demand without proper planning and communication with partners, including the veteran community, TriWest and Optum, will lead to appointment backlogs. How are you working with partners to ensure you can meet veterans' need for care and have the resources to do so while making sure veterans don't end up on long waitlists again?

Response: To ensure that community providers, meet the Veterans' needs for care and have the resources to do so while making sure that the Veterans receive timely care, the VA has provided the following guidance:

a. Converting Routine in-Person Appointment to Telehealth
b. Extending Community Care referrals to expire on September 30, 2020. Additional information can be found at the following link:

- https://content.govdelivery.com/landing_pages/16201/3f46b9fc267d423660be1429190725a5#ICYMI1June
    c. Engaging Third Party Administrators to expand provider enrollment: VA is working with the Third-Party Administrators (TriWest or Optum) to continue to expand enrollment in VA's network. This will allow VA to continue to enhance partnerships and build a robust network of compassionate and dedicated providers for Veterans.
    d. More information is available on the following website: https://www.va.gov/COMMUNITYCARE/providers/COVID-19_Guidance.asp

Question 5. In the FY 21 budget, 65% of the information technology (IT) allocation is dedicated to maintaining legacy systems and infrastructure. What systems has VA identified that need updating, in what priority, and does VA have enough funds to continue to invest in updating outdated systems to ensure it can best deliver benefits and health care services? What has the coronavirus pandemic taught VA about its needs to continue investing in technology and how does that influence the proposed budget for FY 21 and beyond?

Response: VA, in conjunction with OIT, continues to refine the list of products that require modernization, but the overall effort is hampered by a lack of funding. OIT is working on a comprehensive plan to address VA technical debt and ensure that efforts to realize IT modernization can begin, and more importantly, be completed with adequate funding. OIT has recognized the impact of significant underinvesting in IT infrastructure and systems and has created an Infrastructure Readiness Program to address the timely replacement of technology in accordance with standard life cycle refresh methodologies.

The COVID-19 pandemic accentuated the need for scalable IT service capabilities to serve key customer demand areas such as telehealth and telework. IT infrastructure dependencies that support the remote end user experience are the underpinning technologies being targeted by VA infrastructure modernization efforts. The COVID-19 supplemental appropriation has allowed VA to accelerate our modernization efforts in these key areas such as bandwidth, remote access infrastructure, and scalable cloud-based platforms.

For VBA, mandatory (steady state) Sustainment is projected to be 15-25% based on the FY21 baseline, but no firm numbers have been provided to date.

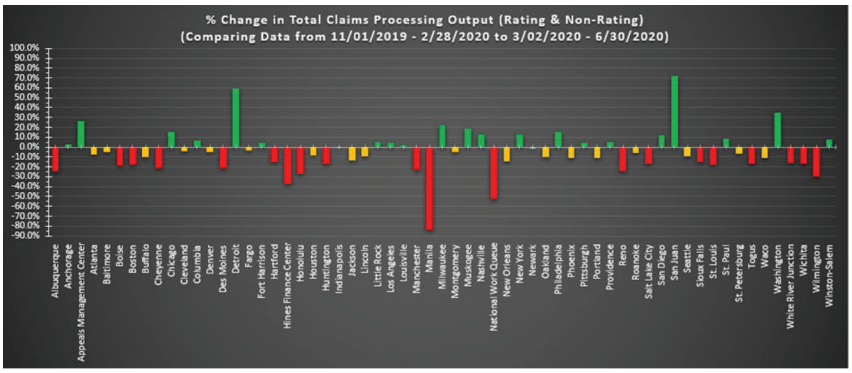
FAS Modernization and BIRLS are Franchise funded so those are not listed here; however, here is a list of VBA legacy systems that are slotted for updates and/or retirement activities in FY2021 that Architecture is tracking:

1) Veterans Benefits Management System (VBMS)
2) SHARE (research/analysis phase and will be a multi-year project)
3) VETSNET (multi-year project – includes MAP-D, SPP, AWARDS, among others that are in planning/research)
4) Work Study Management System (WSMS) (EDU)
5) Life Insurance Policy Administration Solution (LIPAS)
6) Web Loan Guaranty (WebLGY) / VIP / LGY Hub

- There are several highly complex legacy systems which support VBA's operating infrastructure for over 25,000 end-users who process benefits for Veterans within VBA's eight programs/VBA Business Lines. This includes Disability Compensation, Pension, Fiduciary, Veteran Readiness and Employment, Insurance, Office of Administrative Review/Appeals Management, Education, and Loan Guaranty.
- VBA and OIT have been jointly planning through the Legacy Systems Modernization workgroup on projections of business and IT needs to decommission legacy systems in order to enable the return on investment of automation, modernization, and reallocating of human capital to do more complex benefits work for Veterans.
- If the 65% of OIT's allocation funding does not continue to be allocated to maintaining VA Legacy systems supporting VBA's processing of all benefits types to Veterans, then operations will discontinue, and benefits will discontinue to 6.5 million Veterans and Beneficiaries.
- The continued allocation of this funding also enables the plans and execution strategies to take place in order to discontinue the several disparate procedures on legacy systems which require significant workarounds and overly complex manual procedures in order to accomplish day-to-day tasks providing benefits. This includes all VBA Legacy Systems.
- There are modernization and automation efforts underway, however until fully implemented this funding of legacy systems needs to continue in order to sustain data integrity, processing within current state of operations to process benefits, and supporting the human capital of those in VBA's 56 regional offices delivering outcomes for the 6.5 million Veterans and beneficiaries.

Investing in New Technology:

VA's ability to remain operational during the coronavirus pandemic is a testament to its current technological investment. A valuable COVID-19 takeaway is the importance of being proactive instead of reactive. VA's attempt to enable a remote workforce was successful due to an effective telework strategy being implemented prior to the government's social distancing mandate. Success was measured by examining the number of IT related major incidents, as well as claims processing performance both prior to and after users began exclusively working from home. VBA production disruptions have decreased approximately 32% and the combined average number of claims processed for both rating and non-rating has remained within a 0.5% threshold since working remotely. In this specific instance we succeeded; however, it is impossible to predict the future and we have no way of knowing if the next disaster will be similar or completely different from what we have previously encountered. While acknowledging the importance of maintaining legacy systems and infrastructure, allocating funds towards the expansion of new technologies is paramount. Given the unforeseeable nature and detrimental effects associated with events such as these, we must remember resilience is dependent on preparation and a lack thereof could lead to a breakdown in Veteran services.



Question 6. The FY20 joint explanatory statement for Military Construction, Veterans Affairs, and Related Agencies required the VA to study the growing number of homeless women veterans and conduct a gap analysis to determine why existing VA homelessness prevention programs are unable to meet the need of homeless women veterans. When does VA plan to provide a copy of this report to the Committees on Appropriations? Will the findings in the report take into account how the coronavirus pandemic has affected the number of homeless women veterans and the ability of VA homelessness prevention efforts to meet this increased need?

Response: The VHA HPO previously commented on proposed legislation requesting a gap analysis on homeless women Veterans, but we have never received a formal request for action to complete one. HPO does not agree with the contention that "VA homelessness prevention programs are unable to meet the need of homeless women Veterans". In fact, the percentage of women served by our primary homelessness prevention SSVP program exceeds the percentage of women in the homeless Veteran population, as well as the percentage served by all VA homeless programs. HPO believes that women Veterans who are homeless or at risk for homelessness face unique risks and challenges, and all of our programs must be flexible, adaptable, and responsive in order to most effectively meet their needs.

Question 7. Many state's Departments of Veterans' Affairs are considering making cuts to Veteran Benefit Counselor (VBC) programs, due to an overall decline in state revenues due to the economic disruptions caused by the coronavirus. Should these cuts remain permanent, does VA have sufficient staff and resources to help veterans navigate VA benefit programs? What resources does VA currently provide that could help state Departments of Veterans' Affairs and the veterans they serve, deal with a reduced VBC workforce?

Response: VA's Veterans Benefits Administration (VBA) fulfills its statutory obligations under 38 U.S.C. § 7703(5) and 38 U.S.C. Chapter 63 through a variety of means to include in-person and digital outreach. A part of those statutory obligations are required under 38 U.S.C. § 6306 (c) and (d) which require the cooperation and use of services of any federal department or agency or

any state or local governmental agency or recognized national or other organization and where appropriate and to make referrals to any federal department or agency or state or local governmental unit or recognized national or other organization.

Reductions in funding for state VBC programs could impact the level of cooperation and referrals VA is able to make to state organizations. However, in FY 21, VBA will be strengthening its special emphasis outreach and claims processing capabilities by reallocation of 112 FTE for these activities. They will serve as dedicated coordinators focused on support for Veterans with specialized needs, such women, homeless, and minority Veterans, as well as survivors of military sexual trauma. The addition of these coordinators will enable more one-on-one support for these Veterans, a greater VBA presence at local community events, which directly supports states. This will also support a deeper relationship with the Veterans Health Administration to ensure warm hand-offs and better coordination between a Veteran's care team and disability claims staff.

Additionally, dedicated training and development will be provided to ensure the coordinators are empowered to provide compassionate and consistent service to Veterans in these sensitive and high-priority areas. As with the Solid Start initiative, these FTE will be sourced internally based on decreased resources required to process legacy appeals. It is expected that these FTE will increase VBA's outreach footprint to these specific groups through specialized claims clinics that will allow for timely processing of their claims and keeping them well informed throughout the process.

As the level and scope of reductions in state resources is not fully known, VA cannot speculate as to the full impact it may have on its own resources from a workload standpoint at its regional offices. However, as noted above, it may impact VA's ability to utilize the services of state agencies and make proper referrals to those agencies. VA will closely monitor the reduction of state resources and continue to adjust accordingly to meet the needs of Veterans.

Senator Mike Rounds

Question 1: Please explain the department's decision to decrease its requested funding for the VA Rural Health Initiative this year by 10%, or from $300 million in FY20 to $270 million in FY21?

Response: The VA Office of Rural Health (ORH) budget line addresses specific projects related to rural Veterans, not overall rural Veteran care. As VA increases budgets in other areas, such as Connected Care, the need for rural health-specific projects decreases. VA recognizes the needs of rural Veterans and demonstrates its prioritization of this need through more than $24 billion in obligations associated with rural Veteran access to care.

Senator Dan Sullivan

Question 1. As we head into the NDAA process, I plan to introduce an amendment of a bill I have already introduced (S.2328) that authorizes the DoD and VA to enter into agreements for the planning, design, and construction -- or leasing -- of facilities to be operated as shared medical facilities. Consolidation, especially in places like Alaska, would eliminate redundancies, would ensure that DoD specialists are well utilized, serve more veterans and ultimately provide a cost savings to both agencies. Can you speak to the VA's views on moving towards a more comprehensive consolidation of VHA-DHA resources?

Response: VA and the Department of Defense (DoD) partnered in responding to House Report 116-120, page 159, to accompany H.R. 2500, the National Defense Authorization Act (NDAA) for the fiscal year (FY) 2020 report (Report) which DoD submitted on May 22, 2020. A copy of the report is provided for your convenience.

FY20 RTC on HR 2500 - Co-Location c

- The Report provides information on the progress for co-located facilities and shared services accomplished principally through sharing agreements.
    - The Report underscores the need for legislation that will enable the Departments to expand upon the existing collaborative relationship and permit the construction and leasing of shared medical facilities when it is appropriate to do so for the benefit of Taxpayers, Veterans and Service Members.
- The VA/DoD Medical Sharing Office (MSO); VHA and the DoD/VA Program Office (DVPO); and the Assistant Secretary of Defense for Health Affairs (ASDHA) serve as the primary liaisons for their respective Departments' VHA/DoD joint sharing initiatives.
    - MSO and DVPO provide senior-level leadership and direction for the support and accomplishment of all health care related VHA/DoD Joint Strategic Plan goals, objectives and performance measures through the use of medical resource sharing agreements.
- VA and DoD are constantly seeking opportunities for greater sharing of medical resources, to include facility space.
    - DoD is partnering with VA in VHA's Market Assessments outlined in VA MISSION Act (2018) § 106(a)(1)(D), which states "Each market area assessment…shall include

the following…(D) An assessment obtained from other Federal direct delivery systems of their capacity to provide health care to veterans."

- The outcomes from each of the market assessments will drive market optimization and capital plans that align with the regional Veterans Integrated Service Network (VISN) and National DoD/VA Strategic Plans.

Question 2. How could Congress support further VA-DoD integration? What do you view as next steps?

Response: VA and DoD do not currently have legislative authority to conduct joint planning under either title 38 or title 10, United States Code. VA and DoD have submitted combined legislation to provide the authority for joint planning beginning FY 2014 through FY 2021. Most recently, the proposal was transmitted to Congress for consideration for inclusion in the NDAA for FY 2021.

Enacting the Combined Legislation, currently proposed for FY 2021, will provide inherent authority for both Departments to transfer and accept funds appropriated for the planning and design, major (authorized) and minor construction, and leasing of shared medical facilities. This will eliminate a major obstacle to collaboration on joint capital projects, thereby improving the efficiency, accessibility and cost-effectiveness of healthcare delivery for Veterans, Service members and taxpayers.

Question 3. Sec. Wilkie has stated before, that "funding should go where the Veterans are." I'm concerned that the current Veterans Equitable Resource Allocation (VERA) model preferentially supports larger facilities within a VISN and makes it difficult to accommodate the meaningful growth of a smaller facility in a short period of time – rapid growth such as we've seen in Alaska over the past four years. Can you speak to the current regional budget allocation process within VHA, particularly the VA's calculation of Patient Weighted Work for the Alaska VA Healthcare System?

Response: To distribute funds from the VISN level to the VA medical centers (VAMC), VA uses the Medical Center Allocation System (MCAS), which accounts for the patient population resource intensity through the Patient Weighted Work (PWW) metric. This resource intensity of the medical centers patient population is measured by multiplying medical centers prorated person (PRP) with the national value assigned to each of the diagnosis classes in the VERA patient classification system.

Between FY 2016 and FY 2019, Alaska's total allocation (General Purpose & Medical Community Care) grew 40%, from $154 million to $216 million, with Medical Care in the Community (MCC) allocation growing 38% and General Purpose growing by 42%. The patient growth in that time period is 10%, with 24% growth in patients who sought care in the community and 9% growth in the in-house care. However, the full-time equivalent (FTE) growth between FY 2016 and FY 2019 is 20% and does not align with 9% patient growth in in-house setting. In both VERA and MCAS, allocations follow the patients and not the staff. This disparity in FTE vs. patient growth suggests that it is a hiring issue rather than an allocation issue. If the patient growth tracked that of the FTE growth, allocations would have been higher than what was allocated in FY 2019. (*See* Table 1)

Table 1

	FY 2016	FY 2019	% growth between FY 2016 & FY 2019									
	Patients	FTE	Salary ($000s)	Allocations ($000s)	Patients	FTE	Salary ($000s)	Allocations ($000s)	Patients	FTE	Salary	Allocations
In-house	20,347	586	$72,335	$65,940	22,178	703	$90,730	$93,346	9%	20%	25%	42%
Community	15,474	0	$0	$88,795	19,223	0	$0	$122,771	24%	0%	0%	38%
Total	22,000	586	$72,335	$154,735	24,213	703	$90,730	$216,116	10%	20%	25%	40%

Alaska relies significantly more (62% of their allocation is in MCC appropriation) on purchased care and spends more on purchasing similar services than other VAMCs. VERA and MCAS mitigates these specialhigh costs for purchasing care by allocating a portion of MCC funds to Alaska. The allocation was $34 million in FY 2019 and $56 million in FY 2020.

Question 4. Does the current funding model appropriately accommodate facilities that undergo rapid growth and if not, what adjustments can be made so that increased hiring and productivity are properly programmed into the annual budgets of these facilities?

Response: Yes. MCAS has an initiatives section which allows VISN management to precisely identify local emergent changes and designate funds accordingly. These changes can include rapid changes in workload patterns, new initiatives, and other staffing and structural changes that are not accounted for by PWW.

Senator Marsha Blackburn

Telemedicine

Question 1. Secretary Wilkie, how has the Department of Veterans Affairs (VA) utilized the $2.2 billion appropriated in the CARES ACT for telehealth services?

VA Response: VA has allocated CARES Act funding to manage the exponential growth of the Telehealth VA Video Connect program advanced by the COVID-19 pandemic. As of July 27, 2020, VA has allocated approximately $57.8 million for clinical support equipment and peripherals; provider training; 24/7 help desk support and expansion; additional application licenses; and application design development and implementation. Table 2 itemizes the purchased items.

Table 2

FY 2020 COVID-19 Obligations/Expenses
VA Video Connect (VVC) Provider Equipment (Headsets and Webcams)
Patient iPad Tablets with Data Plans (6,000)
DigiCert SSL Certificates (Add Capacity to *Care.va.gov*)
Memorandum of Understanding for Additional Training Staffing
National Telehealth Help Desk 24/7 and Additional Staff
Provider iPad and Accessories
Patient iPad Tablet
Telehealth System and App Release, Implementation and Deployment
Provider Apple iPads (9,000)
Patient Apple iPads (4,000)
Provider DELL Monitors
NTTHD/MSD Additional Help Desk Staff (30) thru 8/31/20
SMS Gateway Services Expansion
Remediation Optional Tasks (App Development and Implementation)
DigiCert SSL Certificates (Add Capacity to Care2.va.gov)
Adobe Connect 2,000 Additional Licenses
Telehealth Clinical Technician Optional – Contract # 203
iPad Pro Distribution @ Mobile Service Help Desk
Memorandum of Understanding VC-CORE - Mental Health Support
Authority to Operate (Stoneware, AIP, CHAT)
Patient iPhones for Homeless
Patient iPads (7000)
Project Integration and Program Support
CHISS Optional Tasks – Contract # 224

Question 2. Secretary Wilkie, how is the VA capturing the veteran experience with telemedicine, and is VA soliciting direct feedback from the veteran and the provider?

Response: VA captures Veteran experience information using the VSignals. Seven different VSignals surveys capture Veteran experience data for multiple aspects and types of telehealth Veteran appointments. Survey information is captured for aspects of scheduling and the appointment for all three telehealth modalities (Synchronous, Asynchronous and Remote Patient Monitoring). Since January 2020, over 290,000 surveys have been sent, with approximately 50,000 responses received (17% response rate). Note: These figures include all three modalities. Additionally, VA uses a similar methodology to solicit feedback from providers who use telehealth for patient care. VA sends surveys to novice and experienced telehealth providers about their experience providing telehealth services. Since January 2020, approximately 32,000 surveys have been sent, with approximately 3,500 responses received (11% response rate).

Question 3. Secretary Wilkie, in what ways, if at all, do you anticipate the VA to adopt telemedicine as the primary platform of care delivery post-pandemic?

Response: VHA wants Veterans to have options for how they receive their health care based on their preferences. VA's goal is to make sure that telehealth is one of those options when preferred by the Veteran and deemed medically appropriate by their health care professionals.

To forecast future needs in alignment with VA strategic plans, VA continues to review and analyze the exponential growth of telehealth services precipitated by the COVID-19 pandemic to compile lessons-learned from providers, Veterans and their caregivers' experiences. To understand patient experiences and outcomes related to the use of virtual care during COVID-19, VA has established a research core to analyze virtual care tools in use. The following are related facts in the current analysis:

- VA conducted structured interviews with Veterans from across the Country who had a video visit during the COVID-19 pandemic and found that Veterans preferred video over phone calls, noting that it made them feel more connected to their providers.
- From March 1 to May 31, 2020, there has been an increase of 401,200 (560,300 to 961,500) Veterans using telehealth. This represents 16% of all Veterans who receive care at VA.
- There were 21,674 Providers in Primary Care, Mental Health and Specialty care that had provided at least one telehealth visit by the end of February 2020. At the end of May 2020, 30,273 providers had completed at least one telehealth visit, an increase of 8,599 providers. At the end of May 2020, 87% of Mental Health Providers, 83% of Primary Care providers and 42% of Specialty Care providers had provided at least one telehealth video visit to a Veteran's home or other offsite location.
- Week-over-week telehealth video appointments have increased by 1170% since February 2020, increasing from approximately 10,000 appointments a week in early February to more than 127,000 appointments during the last week in May 2020.
- To prevent COVID-19 exposure, many VA providers are teleworking; completing telehealth video sessions with Veterans from their homes using personal equipment or Government-furnished equipment. The ability to do this, particularly in COVID-19 hotspots, has resulted in sustained access to care across multiple modalities (secure messaging, telephone, video and mobile applications) and many specialties.
- Remote Patient Monitoring-Home Telehealth is a program where Veterans enroll and are monitored remotely using VA-provided technology from their home or other remote location. The Veteran responds daily with biometric data and answers to questions about their health status. Since the arrival of COVID-19, specific Disease Management Protocols were developed that monitor Veterans for the symptoms related to COVID-19. Through July 13, 2020, more than 5,000 Veterans were monitored daily for COVID-19 symptoms using this program.

Question 4. Dr. Stone, in addition to supplementary appropriations, the CARES Act includes a provision that allows VA to enter into short-term agreements with telecommunications companies to expand tele-mental health services for isolated veterans during the public health emergency. In April 2020, I co-signed a bipartisan letter encouraging the VA to fully implement this necessary authority, but there seems to be a lack of urgency in execution. Has the VA developed a comprehensive plan to fully utilize this authority?

Response: VA is seeking additional private-sector partners to help support Veteran access to internet services. A Request for Information (RFI) was released publicly on July 29, 2020, to garner input and ideas. VA has previously established successful partnerships with several private-sector companies for this purpose including with Microsoft, Verizon, T-Mobile, SafeLink by Tracfone and Sprint (now owned by T-Mobile) and will be announcing additional partnerships soon. Through the RFI, VA intends to find additional partners ready to support Veterans' access to telehealth services.

Electronic Health Records Modernization (EHRM)

Question 5. Secretary Wilkie, due to COVID-19 response measures, the EHRM process has been put on hold, to include training on the Centralized Scheduling Solution (CSS). Does this delay warrant a change to the FY21 budget request if, due to the emergency pause, the funds cannot be utilized?

Response: Given COVID-19 schedule impacts and VA's Office of Electronic Health Record Modernization (OEHRM) efforts to prioritize the health and safety of Veterans and clinicians, the FY 2021 funding request remains unchanged. OEHRM is revising the wave deployment strategy, while adhering to the 10-year deployment timeline and the original program life-cycle cost estimate (LCCE). OEHRM will realign its wave construct to implement the new EHR solution at small and medium facilities in the VISN first, deploying to larger and more complex facilities later in the wave, avoiding fragmentation of the VISN. OEHRM's shift in focus to the Centralized Scheduling Solution (CSS) means funding an emergent requirement of procuring additional training staff and training facilities to adhere to social distancing guidelines, rules and regulations. Additional funds will be required to develop virtual training environments in preparation for future deployments and to minimize COVID-19 impacts.

Community Care

Question 6. Dr. Stone, in our last hearing on Community Care, we spoke about the unacceptable backlog – of over 2 million past due claims – that VA has with provider reimbursements. What improvements has VA made to the Community Care reimbursement process over the last few months to reduce the backlog?

Response: VA has made significant improvement with aged claim reduction. From the previously discussed backlog of over 2 million claims, VA's aged inventory is now at 1.08 million claims, as of July 27, 2020.

Question 7. Dr. Stone, does the funding requested in VA's FY21 budget, and that appropriated in the CARES Act, provide resources to make demonstrable progress toward clearing the backlog?

Response: The aged inventory has been reduced by over 1 million claims this year. The CARES Act provided significant resources to support VA's response to the COVID-19 pandemic. Between the CARES Act and our FY 2021 budget request, VA should have resources to meet the need. VA will continue to monitor and notify Congress, should estimates change.

Question 8. Dr. Stone, when do you anticipate having these backlogged claims completely eliminated?

Response: By the end of FY 2020, VA will have further reduced the backlog and anticipates being at a normal operating level of under 650,000 claims in the aged inventory.

CARES Act Supplemental Appropriations

Question 9. Mr. Rychalski, in dollars, how much of the funding appropriated to VA by the CARES Act has been utilized, and to what programs or activities is VA focusing the yet-to-be-expended monies?

Response: VA has obligated $2.69 billion of CARES Act funding as of July 1, 2020. VA plans to use the remaining funds to care for Veterans impacted by COVID-19, including procuring equipment and supplies at VAMCs; maintaining expanded telehealth capabilities; and providing support for Veterans experiencing or at risk of homelessness due COVID-19.

Senator Kevin Cramer

Question 1. I have a veteran in North Dakota who had VA addiction recovery treatment lined up in another state. However, with the coronavirus it was not feasible for him to travel out of state. With his only option being in-state facilities, he lined up treatment at a residential facility in North Dakota. However, the VA determined it could not cover the treatment because, as my staff was told, the VA will not reimburse for residential or in-patient treatment. With no out-patient options in state, this veteran had to choose between waiting an unknown amount of time for coronavirus restrictions to be lifted or pay out of pocket for this time-sensitive treatment. These rigid policies failed this Veteran, so my office reached out to the VA. After a month and multiple follow up emails, we received a response. Unfortunately, the response did not get into detail about the specific veterans situation and denied the existence of any such issue.

> *Question 1a.* Does the VA reimburse for residential treatment services? If not, why not (especially in cases in which it is the veterans only option)?

Response: To the extent a Veteran is eligible to receive residential treatment services in the community under the Veterans Community Care Program established by 38 U.S.C. § 1703, the Veteran has elected to receive such services in the community, and appropriations are available, VA will obtain such services in the community for the Veteran, if feasible. Under such circumstances, the community provider or facility is paid directly by VA (or a VA contractor) and the Veteran is not involved in payment and subsequent reimbursement. With regard to whether VA would be able to pay for residential treatment services furnished in a particular non-VA facility, that would depend on several factors, including whether the facility meets all legal and policy requirements (e.g., quality of care standards) for furnishing such community care and whether VA has or is able to enter into a contract or agreement to procure such services from that facility. We would encourage this Veteran to contact the local VA community care office to discuss the options available to them in seeking and obtaining treatment.

> *Question 1b.* Is over a month an acceptable timeframe for the VA to get back to a committee member's office on a time sensitive casework issue?

Response: VHA aims to answer all casework issues no later than 15 business days from receipt, and we regret that this response took over a month and did not appropriately resolve your and the Veteran's concern. We will work with VISN 23 and the facility to review this case and ensure follow-up and closure with your office.

> *Question 1c.* Will your staff commit to working with my office on the specifics of this veteran's case?

Response: Yes. VHA will ensure that VISN 23 and the facility are in contact with your staff regarding this Veteran's case.

Question 2. Can you provide my office with an update on the VA Compassionate Care and Innovation Hyperbaric Oxygen Therapy (HBOT) treatment pilot project?

Response: The VHA Center for Compassionate Care Innovation (CCI) program is currently facilitating a small-scale clinical demonstration project on the use of HBOT for Veterans diagnosed with posttraumatic stress disorder (PTSD), with or without comorbid traumatic brain injury (TBI). The purpose of the demonstration project is to evaluate the provision of HBOT for PTSD in a clinical context, including identifying necessary resources, barriers and feasibility of referring Veterans for off-label use of this treatment. The project is not comparing HBOT to other forms of PTSD treatment; it does not restrict use of evidence-based or other treatments concurrently; it is not considered a research study; and it is not intended to add to the scientific body of evidence on the health outcomes of using HBOT to treat PTSD. Currently, the following five VA facilities are participating in the project:

- VA Northern California Health Care System, in cooperation with David Grant Medical Center, on Travis Air Force Base, DoD;
- Eastern Oklahoma VA Health Care System, in cooperation with Tulsa Wound Care and Hyperbaric Center, at Oklahoma State University Medical Center;
- South Texas Veterans Health Care System, San Antonio, Texas, in cooperation with Nix Health, a community provider in San Antonio, Texas and Military Medical Center, Joint Base San Antonio-Fort Sam Houston, DoD;
- James A. Haley Veterans' Hospital, Tampa, Florida, in cooperation with Undersea Oxygen Clinic and the Wound Healing Institutes, community providers in Tampa, Florida; and
- Fargo VA Health Care System, in cooperation with Healing with Hyperbarics of North Dakota, PLLC, a community provider in Fargo, North Dakota.

As of July 15, 2020, 45 unique Veterans have been referred for treatment across all 5 sites. Please note the following statistics:

- 18 Veterans have completed HBOT treatment under this pilot;
- 14 Veterans dropped out during their treatment plan;
- 6 Veterans cancelled their treatment plan (dropped out) prior to starting HBOT treatment;
- 5 Veterans are currently receiving HBOT treatment; and
- 2 Veterans have been referred and have not yet started HBOT treatment.

The most common reason cited by Veterans for dropping out during or prior to treatment was the significant time commitment required to attend appointments 5 days per week for 8 consecutive weeks. The VA Northern California Health Care System pilot site temporarily postponed referring Veterans for this project starting in March 2020, due to COVID-19 impact on the VA facility and DoD facility providing HBOT treatment. Some HBOT clinics at the other four locations experienced temporary service disruptions due to COVID-19 that, as of the time of this report, have been resolved. No adverse events have been reported.

Question 3. Does the VA have standardized metrics as they research HBOTs efficacy? What are these metrics?

Response: American health care or the Federal Government does not have standardized metrics and does not have any new studies for HBOT efficacy.
CCI's HBOT pilot program is not considered research and is not collecting data to determine HBOT efficacy for treatment of PTSD symptoms or any clinical diagnosis. CCI is surveying VA providers at the pilot sites for their qualitative feedback, regarding barriers and supportive factors that impact implementation of this demonstration project, in order to address operational challenges that arise from facilitating off-label HBOT treatment. The pilot sites are reporting the number of referrals, status of referrals, PCL-5 scores and PHQ-9 scores (when appropriate) as part of the implementation plan for the pilot. VA providers use these metrics to assess their patient's health in accordance with standard clinical practice and for operational assessment of the pilot status, not as measurement of HBOT efficacy.

Question 4. Has the VA looked at partnering with private entities to conduct HBOT research?

Response: VA has not been contacted by any private entity to jointly conduct a clinical trial employing HBOT as a therapy for TBI. None of our VA investigators have brought forward an application where they are collaborating with a private entity to conduct an HBOT clinical trial.

Question 5. With the respiratory impact of COVID-19, has HBOT been looked at as a possible therapy for veterans?

Response: No. The benefit of HBOT is the higher amount of oxygen that can be carried outside hemoglobin, dissolved in the plasma. However, the oxygen still has to come through the lungs to get into the plasma. It is the lung disease that prevents uptake of oxygen and the hyperbaric state would not

change the lung disease and blockage of oxygen exchange in the lung. There is no rationale for the use of HBOT for the treatment of COVID-19.

Compensation Service

Medical Disability Examinations

VBA Contract Examination Restart Plan

May 2020

Veterans Benefits Administration

VA | U.S. Department of Veterans Affairs

Medical Disability Examination Program: VBA Contract Examination Restart Plan

Contents

Executive Summary

In response to the COVID-19 pandemic, VBA temporarily suspended in-person disability examinations on April 3rd, 2020 to eliminate the risk of exposure to Veterans and providers. Additionally, the Veterans Health Administration (VHA), redirected C&P disability examination processing to focus efforts on COVID-19 medical support.

VBA understands that these benefits may represent life-sustaining income, and the government has identified measures to maximize safety in essential operations. The services we provide are exempt from the Shelter-in-place order, however, VA is monitoring the safety requirements and social distancing protocols from each state as well as the CDC recommendations to mitigate risk to our Veterans and providers.

In anticipation of Federal and state restrictions being rescinded and/or relaxed in the coming weeks, the Medical Disability Examination Program Office (MDEPO) is issuing guidance regarding the conditions that must be met for Vendors to receive approval to resume in-person disability examinations. Given these conditions, MDEPO is requesting that Vendors submit comprehensive plans for the resumption of in-person examinations.

One key issue is capacity of providers vs. Veterans' need to have their examinations completed in a safe and timely manner. Because systems and facilities are unique and readiness may vary, MDEPO reserves the right to assign workload among Vendors based on Vendor reported and demonstrated capacity and will communicate this status to individual Vendors.

I. Where We've Been

The Administration began to receive reports of the emergence of a novel coronavirus outbreak, COVID-19 as early as January 2020. As more information came to light and the virus continued to spread, the World Health Organization (WHO) declared COVID-19 a global pandemic in March 2020, which lead the MDEPO to direct the halt of all in-person examinations. Below is a summary of related dates and activities:

- **3/12**: Required daily updates regarding affected Veteran appointment information from Vendors to track COVID-19 impact; Directed all vendors to hold (not cancel) affected Veteran appointments if the appointment could not be completed
- **3/23-3/24**: Required daily reporting from Vendors on clinic and provider availability; VBA provided Vendors refresher Acceptable Clinical Evidence (ACE)/Tele C&P training
- **4/2**: VHA released a memorandum advising all in-person C&P examinations will be cancelled and returned to VBA, while VHA diverts all resources to COVID-19 operations.
- **4/3**: VBA directed Vendors to stop conducting in-person exams due to COVID-19 pandemic; Vendors advised to maximize ACE and tele-medicine modalities to continue operations
- **5/1**: Federal social distancing guidelines expired
- **5/21**: VA provides guidance to vendors on immediately restarting in person exams in 20 lead site locations.

II. Resumption Criteria

MDEPO, in conjunction with Veteran Benefits Administration (VBA) and VHA guidance, determined criteria (subject to change) under which medical disability examinations may be safely conducted. The guidance provided in this document is not intended as a replacement of any contractual requirements and should be considered additional operational guidelines necessary to resume in-person examinations during the COVID-19 pandemic. When it is safe to do so, MDEPO will provide approval to Vendors to resume in-person exams. This decision will be made based on CDC, Federal, and State guidelines and guidance from public health officials, VBA Contracting Officer, and VA Leadership.

Until in-person examinations have been approved to resume, VA expects Vendors to maximize the use of ACE and Tele C&P examinations. Veterans who do not wish to attend Tele C&P exams will be provided the opportunity to opt-in to attending in-person examinations, and each Veteran's decision will be tracked to ensure effective examination scheduling. Veterans who wish to delay in-person exams due to concerns about COVID-19 exposure will be provided an opportunity to reschedule at a later date.

Vendors must request approval and receive written authorization from MDEPO to resume in-person examinations. As local shelter in place orders are relaxed/lifted, Vendors may request MDEPO approval to resume conducting in-person examinations by providing a COVID-19 Vendor Operating Plan that indicates that the following conditions are met:

1. Expiration of state shelter in place orders; and/or
2. State-level Executive Order that authorizes a state to resume elective medical care/outpatient in-person examinations in accordance with individual official state.gov websites and the following website: https://web.csg.org/covid19/executive-orders/; and/or
3. VA identified "Lead Site" operating area
4. COVID-19 Vendor Operating Plans:
    a. Vendor Personal Protective Equipment (PPE) acquisition and distribution plan, including a certification of an adequate PPE supply to support examination volume at all operating Vendor facilities
    b. Vendor will produce a written sanitation plan that addresses all phases of examination (Pre-Appointment Pre-Exam, During/Post Exam) for the Vendor clinics and the Vendor's subcontracted provider network which is in compliance with their local/district health department guidelines
    c. Vendor will produce an Implementation Plan which details how they will execute each phase of the examination process, to include scheduling, Veteran arrival to clinic, screening, pre examination, during examination, and post-examination
    d. Identification of counties within each state where the resumption of in-person examinations is being requested
    e. These plans will be updated regularly

COVID-19 Vendor Operating Plan packages should incorporate the above criteria, as well as Vendor processes, procedures, and capacity information. This package will be submitted electronically to the MDEPO Contract Exam Mailbox at ContractExam.VBAVACO@va.gov, and the following

individuals will be copied on all email submissions: Pamela.Miller3@va.gov ; Erin.Gittens@va.gov ; John.Detty@va.gov.

Provider Site-Specific Guidelines:

MDEPO will require all vendors to provide sufficient evidence to demonstrate that they are adhering to the below guidelines once in-person examinations are approved to resume. Reporting requirements will be communicated to vendors upon approval of resumption of in-person examinations and will subject to change at MDEPO's discretion.

a) Arrange site space to support social distancing

- Veteran intake procedures to include:
  - Greeter/Screener (with appropriate PPE) at the door who will keep account of Veterans entering the facility
  - In the event that a facility is unable to accommodate all scheduled appointment attendees while adhering to social distancing guidelines, a waiting line outside of the facility will be established which ensures all Veterans are able to maintain a distance of at least 6ft apart from one another
  - Vendor staff will provide further explanation of PPE and social distancing requirements to Veterans as needed
  - Social distance (6 ft) seating and limiting facility capacity and/or the ability for Veterans to wait in their vehicle until their appointment time
- Veterans must acknowledge and adhere to PPE and social distancing instructions during the entire clinic appointment
- PPE provided to Veterans at the time of check-in
- Hand sanitizer stations at easily accessible locations throughout the facility
  - If hand sanitizer is not available, hand washing stations should be made easily available to all Vendor staff and facility attendees
- Posted safety protocols throughout the facility, including signage visible prior to entering the clinic/facility
- One-way flow of personnel where possible
- Social distance (6 ft) seating and limiting facility capacity

b) Personal Protective Equipment Use and Supply

- All Vendor personnel must wear appropriate Personal Protective Equipment (PPE) at all times while on-premises
- Vendors must ensure visitors/Veterans wear appropriate PPE at all times while on-premises and during any testing and diagnostic procedures (Vendors must be able to provide appropriate PPE to Veterans)
- PPE and other equipment inventory must include:
  - Eye Protection
  - N95 Respirators (Preferred for HCP)
  - Facemasks (Alternative for HCP)
  - Cloth Face Covering

- Examination Gloves
- Hand Sanitizers
- Temporal Thermometers
- Procedure/Surgical Masks
- Gowns
- Aprons
- Shoe coverings

c) Screening

- Screening will consist of the following elements:
  - Pre-Screening During Appointment Scheduling
    - Veteran vulnerability notification/identification
    - Veteran's willingness to attend
    - Current symptoms
    - Recent exposure to confirmed COVID-19 case (14-day exposure window)
    - Identification and justification of a required accompanying individual/individuals
    - Veteran's willingness to wear PPE during appointment
    - Pre-screening COVID-19 related questionnaire
  - On-Site Screening (All Veterans, attendees, and Vendor staff)
    - Current symptoms
    - Recent exposure to confirmed COVID-19 case (14-day exposure window)
    - PPE requirements
- Vendors will provide MDEPO with their proposed screening procedures and screening questionnaires for review and approval prior to implementation
- Vendors will screen all their staff members to ensure they are symptom-free before starting their duties/shifts
- Vendors will call and screen Veterans prior to the scheduled appointment to ensure they are symptom-free and physically capable of traveling to the clinic site
- All Veterans will complete symptom questionnaire and will be informed that they will be required to receive a temperature check upon arrival. Vendors will document positive symptoms in accordance with CDC guidelines and will inform Veteran as to why their appointment must be rescheduled
- All Veterans will wear the required PPE during the entirety of the appointment. Any Veteran who refuses to do so will be informed that their appointment cannot take place and must be rescheduled
- Veterans will not be accompanied into the facility by any other person(s) unless required to be able to attend their appointment due to a physical, mental, or other qualifying restriction. The facility should be made aware ahead of time if this is the case during the screening process. The accompanying individual and the individual accompanying them will be treated as a single individual when applying social distancing guidelines

d) Incarcerated Veteran Examinations

- Vendors must coordinate with correctional facilities following the requirements provided in the contract, as well as confirm the facility is able to provide a sterilized environment that ensures the safety of the veteran, Vendor personnel, and correctional facility staff
- MDE Vendors must comply with the local department of public health, Federal Bureau of Prisons, and State Department of Corrections polices to reduce the risk of exposure in the correctional facilities
- MDE Vendors must contact the correctional facility to determine if visitor restrictions are in place
- When permitted, Vendors should use ACE and/or Tele C&P examination
- The contract vendor must record all attempts to obtain approval from the correctional facility when scheduling an incarcerated Veteran for a VA disability evaluation

e) Housebound Veteran Examinations

- Vendors must follow the approval procedures in accordance with the contract
- Vendors must follow safety guidelines issued by the CDC, to include the use of PPE as outlined in sections II "(b) Personal Protective Equipment Use and Supply" and "(c) Screening" above

f) Restrictions

- Vendors will ensure no exams or diagnostics are scheduled or occur that require the removal of PPE, including procedures with higher risk of aerosol transmission (e.g. endoscopy, bronchoscopy, pulmonary function test [PFT], etc.) during the COVID-19 pandemic
- Vendors will not operate until facilities comply with social distancing guidelines
- Vendors will not perform any examination and/or diagnostic test on any Veteran with current or recent symptoms (within 14 days)
- Vendors will not allow providers/staff members with current or recent symptoms (within 14 days) to provide services

MDEPO-Directed Process

Below is an outline of the process Vendors will establish and follow for in-person examinations:

a) Pre-Appointment

- Phone screening when scheduling appointment for both COVID-19 symptoms and the Veteran's comfort level for reporting
- A MDEPO-approved screening questionnaire will be included in the appointment letter package sent to Veterans
- Automated phone screening to be completed when conducting the Veteran appointment reminder call
- The Vendor will request that the Veteran come to appointment with a face cover or surgical mask that complies with PPE requirements

b) Pre-Examination

- Provide Veterans the opportunity to be escorted into the check-in area to ensure physical separation from others
- The Veteran will be required to put on PPE face covering provided by the Vendor if unable to bring a personal mask
- The Veteran will be required to sanitize hands (hand sanitizer or washing)
- The Veteran will undergo mandatory screening in a socially distanced and/or isolated location
    - COVID-19 Questionnaire
    - Temperature check
    - Screening for COVID-19 symptoms identified in CDC guidelines

c) During / Post-Examination

- Vendors will sanitize the examination space prior to and immediately following each examination
- A Vendor staff member will escort the Veteran to the examination room to ensure physical separation from other Veterans, Vendor staff, and location visitors
- A Vendor staff member will escort the Veteran to the exit to ensure physical separation from other Veterans, Vendor staff, and location visitors

III. Communications

a) Vendor Tracking and Reporting to MDEPO

MDE Vendors will provide MDEPO with regular reporting on the following elements:

- Appointments that are put on hold due to the Veteran being uncomfortable attending an in-person appointment due to COVID-19 concerns.
- Veterans or staff asked to leave an appointment due to displaying symptoms consistent with COVID-19
- Veterans who were required to reschedule their appointment based due to displaying symptoms consistent with and/or potential exposure to COVID-19 being identified during the pre-screening/screening process
- Non-compliance with any safety protocol by any Veteran, Vendor staff or facility, or Vendor provider/subcontractor staff or facility

b) Communicating with Veterans

MDE Vendors will include the following standard messaging elements when scheduling examinations with Veterans:

- Disability exams are included under essential services
- Explanation of ACE and Tele C&P options (where applicable)
- In-person exams are once again available (following MDEPO approval)
- Exposed or symptomatic Veterans must postpone/reschedule
- Overview of COVID-19 safety protocols that are in effect on-site
- All Veterans must wear the required PPE during the entirety of the appointment. Any Veteran who refuses to do so will be informed that their appointment cannot take place and must be rescheduled.

IV. Best Practice Recommendations

Each Vendor must develop written solutions to ensure they meet the resumption criteria provided in section II: Resumption Criteria of this document. These solutions will be based on individual Vendor systems, sites/locations, and in coordination with individual providers that will be performing Veteran examinations for that Vendor. MDEPO has provided the following best practice recommendations for Vendor consideration when developing their written solutions:

- Communicate early and often with Veterans, providers, and MDEPO
- Screen exam scheduling requests (ESRs) to prioritize, categorize, and schedule
- Recommend additional potential ACE and Tele C&P procedures to MDEPO
- Maximize the use of ACE and Tele C&P
- Cross-train staff in the use and communication of ACE and Tele C&P care
- Extend hours and weekend availability
- Optimize the use of mobile capabilities (with COVID-19 protocol)
- Be prepared for a 2-week (maximum) timeline for restart of in-person exams following date of MDEPO approval
- Tentative scheduling of exams for VA "Lead Site" locations should begin as soon as possible
- Placeholder appointments are acceptable for all other locations pending approval of requested restart plans

V. Planning for the Future

As the MDE program adapts to a new COVID-19 operating environment following the quarantine efforts implemented in early 2020, MDE program is likely to encounter the following once quarantine restrictions are lifted:

- A large backlog of previously scheduled Veteran appointments
- Increased concerns related to COVID-19 exposure resulting in an extended timeframe of lower-than-average examination requests
- A large increase in examination request once a vaccination is implemented and/or COVID-19 cases reduce significantly

Given these factors, MDEPO is requiring that all MDE vendors provide an analysis of workload vs capacity in the following timeframes:

- 30 Days from Restart: Current
- 90 Days from Restart: Recovery
- 120 Days from Restart: Future State

Utilizing the above workload vs. capacity analysis, vendors will provide MDEPO with a workload management plan (WMP) which details the up-to-date procedures that will be employed to ensure the Vendor is able to increase production to address the anticipated backlog of examination requests due to the impact of COVID-19 response actions. This WMP will include the following elements:

- Staffing Plan
    - Current staffing levels
    - Forecast of future staffing needs

- Training Updates
- Quality Reviews
- Process Improvements
- Workload Distribution and Prioritization
- Maximizing ACE/Tele C&P Utilization

The MDE program is continually evaluating the operating environment and has implemented the following internal adjustments to ensure the program is prepared for the future impacts that the sustained presence of COVID-19 present:

- Increasing MDEPO organization capabilities (staff and systems)
- Approving more ACE and Tele C&P examinations to ensure Vendors are able serve as many Veterans as possible while ensuring their safety
- Assessing the program's budget to ensure the necessary funding is available to address the expected backlog and estimated sustained increase in examinations

VI. Conclusion

The MDE program remains committed to the safety and welfare of our Veteran clients, our providers, and our staff. We will continue to work closely with all stakeholders to ensure continuity of services through continued planning, adaptation processes, implementation and utilization of systems, and continued training of our staff and partners.

Veterans Benefits Administration

VBA Contract Examination Restart Plan
Vendor Overview

May 21, 2020

Where We've Been

Below is a summary of COVID-19 related dates and activities which directly impacted MDE operations:

- **3/12**: Required daily updates on affected Veteran appointment information from Vendors to track COVID-19 impact; Directed all vendors to hold (not cancel) affected Veteran appointments if the appointment could not be completed
- **3/23-3/24**: Required daily reporting from Vendors on clinic and provider availability; VBA provided Vendors refresher ACE/Tele C&P training
- **4/2**: VHA released a memo advising all in-person C&P examinations will be cancelled and returned to VBA; VHA diverts all resources to COVID-19 operations
- **4/3**: VBA directed Vendors to stop conducting in-person exams due to COVID-19 pandemic; Vendors advised to maximize ACE and Tele C&P modalities
- **5/1**: Federal social distancing guidelines expired
- **5/21**: VA provides guidance to vendors on immediately restarting in person exams in 20 lead site locations

Phased Restart Approach

	Phase I	Phase II	Phase III
Milestones	• **Prioritize the Oldest Cases First with the Exception of the Already Established VBA Priority Groups Excluding High-Risk Examinations***	• **Outpatient and In-Patient Examinations of Entire Veteran Population with the Exclusion of High-Risk Examinations***	• **Outpatient and In-Patient Examinations of Entire Veteran Population Including All Examinations**
Workload Management	• Prioritize cases with the vendors based on VBA priority groups • Exclude exams that require the removal of PPE with a higher risk of aerosol transmission	• All categories in Phase I to include all Veteran populations • Exclude exams that require the removal of PPE with a higher risk of aerosol transmission	• All categories of Phase I and Phase II to include all examinations

* High-Risk Examinations: Exams or diagnostics that require the removal of PPE, including procedures with higher risk of aerosol transmission (e.g. endoscopy, bronchoscopy, pulmonary function test [PFT], etc.) during the COVID-19 pandemic.

Resumption Criteria

Criteria for Resuming In-Person Examinations

Vendors may request MDEPO approval to resume conducting in-person examinations by *submitting a Vendor Operating Plan which addresses the following elements:

State/Local Criteria:

- ✓ Expiration of state shelter in place orders and/or,
- ✓ Executive Order that authorizes a state to resume elective out-patient medical care in accordance with state guidance
- ✓ VA identified "Lead Site" operating area

COVID-19 Vendor Operating Plans:

- ✓ Vendor Certification of an adequate PPE supply
- ✓ Vendor Written Sanitation Plan per CDC guidance
- ✓ Vendor Implementation Plan
- ✓ Identification of counties where resumption of in-person exams is being requested

*Vendor Operating Plans will be submitted electronically to the MDEPO Contract Exam Mailbox at ContractExam.VBAVACO@va.gov, and the following individuals will be copied on all email submissions: Pamela.Miller3@va.gov ; Erin.Gittens@va.gov ; John.Detty@va.gov.

Provider Site-Specific Guidelines

MDEPO will require all vendors to provide sufficient evidence to demonstrate that they are adhering to MDEPO established guidelines for the following areas:

a) Arrange Site Space to Support Social Distancing

b) Personal Protective Equipment Use and Supply

c) Screening Procedures

d) Operating Restrictions

- Reference (MDE Restart Plan) for specific requirements

MDEPO-Directed Process

1 Pre-Appointment

- Phone screening for both COVID-19 symptoms and the Veteran's comfort level
- A MDEPO-approved screening questionnaire sent to Veterans
- Automated phone screening during the Veteran appointment reminder call
- Request that the Veteran come to appointment with required PPE

2 Pre-Examination

- Provide Veterans the opportunity to be escorted into the check-in area to ensure physical separation from others
- The Veteran will be required to put on PPE face covering
- The Veteran will be required to sanitize hands
- The Veteran will undergo mandatory screening in a socially distanced and/or isolated location
  - COVID-19 Questionnaire
  - CDC COVID-19 Symptom Check

3 During / Post-Examination

- Vendors will sanitize the examination space prior to and immediately following each examination
- The Veteran will be escorted to the examination room to ensure physical separation from others
- A Vendor staff member will escort the Veteran to the exit to ensure physical separation from others

Vendor Communications with MDEPO

MDE Vendors will provide MDEPO with regular reporting on the following elements:

- Appointments that are put on hold
- Individuals asked to leave an appointment due to displaying COVID-19 symptoms
- Veterans who were required to reschedule their appointment due to displaying symptoms consistent with and/or potential exposure to COVID-19
- Non-compliance with any safety protocol
- Changes/updates to COVID-19 Vendor Operating Plans

Vendor Communications with Veterans

MDE Vendors will include the following standard messaging elements when scheduling examinations with Veterans:

- Disability exams are included under essential services
- Explanation of ACE and Tele C&P options (where applicable)
- In-person exams are once again available (following MDEPO approval)
- Exposed or symptomatic Veterans must postpone/reschedule
- Overview of COVID-19 safety protocols that are in effect on-site
- All Veterans must wear the required PPE during the entirety of the appointment

Best Practice Recommendations

MDE recommends that vendors consider the following best practices when developing their COVID-19 Vendor Operating Plans:

- Communicate early and often with Veterans, providers, and MDEPO
- Screen ESRs to prioritize, categorize, and schedule
- Recommend additional potential ACE and Tele C&P procedures to MDEPO
- Maximize the use of ACE and Tele C&P
- Cross-train staff in the use and communication of ACE and Tele C&P procedures
- Extend hours and weekend availability
- Tentative scheduling of exams for VA "Lead Site" locations should begin as soon as possible
- Make placeholder appointments for all other locations pending approval of requested restart plans

Questions

Department of Veterans Affairs

Memorandum

Date: May 22, 2020

From: David R. McLenachen, Executive Director, MDE Program Integration Office

Subj: In-Person C&P Examination Restart

To: MDEPO Contract Vendors

1. **Purpose:** This memorandum informs Medical Disability Examination Program Office (MDEPO) Compensation & Pension (C&P) exam vendors of the resumption of certain in-person C&P examinations effective May 22, 2020.

2. **Guidance:**

    a. On May 18, 2020, the Department of Veterans Affairs began to reintroduce health care services at 20 Veterans Health Administration facilities that have been selected as VHA Lead Sites. See Attachment A.

    b. Effective May 22, 2020, MDE vendors must resume conducting in-person examinations in these Lead Site operating areas, based on their current regional assignments and contractual guidelines. MDE vendors will submit their restart plans to MDEPO for review and approval, which will be discussed in a separate preliminary restart meetings with each vendor. Finally, vendors will ensure their providers are adhering to all MDEPO (see Attachments B and C), state, and local COVID-19 guidelines prior to conducting any in-person examinations.

    c. MDEPO will issue further guidance regarding expanded in-person examinations at other locations as the information becomes available.

3. **Questions:** For questions regarding this memorandum, please contact Roxana Cepeda, Contracting Officer, at Roxana.cepeda@va.gov or the MDE program office at contractexam.VBAVACO@va.gov].

David R. McLenachen

Attachments

ATTACHMENT C

Vendor COVID-19 Sanitation Guidance

Contract examination vendors must deep clean sites at the end of the day, sanitize prior to and in between examinations, and provide certification prior to resuming and/or conducting examinations that adhere to Centers for Disease Control and Prevention (CDC) guidance for cleaning and disinfecting public spaces, workplaces, businesses, schools, and homes per the CDC's website.

- CDC's guidance for outpatient and ambulatory care facilities includes the following:
    - Normal routine cleaning with soap and water will decrease how much of the virus is on surfaces and objects, which reduces the risk of exposure. Routine cleaning of frequently touched surfaces will be implemented in administrative and clinical areas.
    - Disinfection using Environmental Protection Agency (EPA)-approved disinfectants against COVID-19 is critical during the pandemic. Frequent disinfection of surfaces and objects touched by multiple people should be undertaken while wearing gloves and with adequate ventilation of the areas.
    - When EPA-approved disinfectants for COVID-19 are not available, alternative disinfectants can be used (for example, 1/3 cup of bleach added to 1 gallon of water, or 70% alcohol solutions). Do not mix bleach or other cleaning and disinfection products together. This can cause vapors that may be very dangerous if inhaled. Bleach solutions will be effective for disinfection up to 24 hours. Keep all disinfectants out of the reach of children. Read EPA's infographic on how to use these disinfectant products safely and effectively.
    - Infection Control in Healthcare Settings
    - Hand Hygiene
    - Interim Guidance for Outpatient & Ambulatory Care Settings

ATTACHMENT B

Engineering Controls, and Personal Protective Equipment (PPE) Guidelines and Requirements

Contract examination personnel must conduct examinations and greet Veterans with proper PPE. All contract examination personnel will wear masks and gloves, and vendors will provide visiting Veterans with the same upon arrival based on PPE availability, as well as the Centers for Disease Control and Prevention (CDC) and local guidance/policy. All personnel and facility visitors will adhere to social distancing of at least six feet until all parties are utilizing the necessary PPE. PPE stations must include hand sanitation disinfectant or hand washing capability, which must meet the CDC's recommendations and guidance for the utilization and implementation of PPE.

The CDC's and Occupational Safety and Health Administration's (OSHA) recommendations and guidance for the utilization, implementation, and management of PPE include:

- COVID-19 PPE for Healthcare Personnel
- Using Personal Protective Equipment
- Infection Control Recommendations (Section 2. Adhere to Standard and Transmission-Based Precautions)
- Strategies to Optimize PPE Supply
- OSHA PPE Standards (29 CFR 1910 Subpart I)

Note: Examiners may still allow spouses and family members to attend the examination but veterans should be made aware of occupational safety hazards as they relate to COVID-19. Any spouse or family member who attends the examination must also wear a face mask.

PPE Use and Supply

- All Vendor personnel must wear appropriate PPE at all times while on-premises
- Vendors must ensure Veterans and visitors wear appropriate PPE at all times while on-premises and during any testing and diagnostic procedures (Vendors must supply appropriate PPE)
- PPE and other equipment inventory must include:
    - Eye Protection
    - N95 Respirators (Preferred for HCP)
    - Facemasks, including clear facemasks (Alternative for HCP)
    - Cloth Face Coverings
    - Examination Gloves
    - Hand Sanitizers
    - Temporal Thermometers
    - Procedure/Surgical Masks
    - Gowns, aprons, and shoe coverings

ATTACHMENT A

VA Lead Sites

MDEPO authorizes contract exam vendors* to begin conducting in-person examinations in the city/counties that are serviced by the following Veterans Health Administration (VHA) facilities (i.e., VHA Lead Sites):

1. White River Junction VA Medical Center (VAMC), VT
2. Syracuse VAMC, NY
3. Erie VAMC, PA
4. Hershel “Woody” Williams VAMC, WV
5. Salem VA Healthcare System (HCS), VA
6. Ralph H. Johnson VAMC, SC
7. West Palm Beach VAMC, FL
8. James H. Quillen VA HCS, TN
9. Louis Stokes Cleveland VAMC, OH
10. Tomah VAMC, WI
11. William S. Middleton Memorial Veterans Hospital Madison VAMC, WI
12. Kansas City VAMC, MO
13. Central Arkansas Veterans HCS, AR
14. South Texas VA HCS, TX
15. Fort Harrison VAMC, MT
16. Puget Sound VAMC, WA
17. Boise VAMC, ID
18. VA Southern Nevada HCS, NV
19. VA Southern Arizona HCS, AZ
20. Fargo HCS, ND

* MDE vendors will ensure their providers are adhering to all MDEPO, federal, state, and local guidelines prior to conducting any in-person examinations.

Department of Veterans Affairs
Veterans Health Administration
Pharmacy Benefits Management Services
1st Avenue-1 Block North of Cermak Road
Building 37 Room 139 | Hines, IL 60141

VHA PBM Draft Literature Summary on Investigational and off-label Medications for COVID-19

What's New in COVID-19 Pharmacologic Treatment and Prevention? ***Short summary of new literature 7/20/20-7/28/20***

Guidelines

- **The DHHS/NIH COVID-19 guidelines were last updated 7/24/20 – Major updated related to therapy were:**
  - The guidelines committee recommends AGAINST pre or post-exposure prophylaxis for COVID-19, except in the context of a clinical trial.
  - The guidelines recommend AGAINST the use of HCQ + azithromycin or HIV protease inhibitors except in the context of a clinical trial.
  - They recommend that remdesivir be prioritized for hospitalized patients who require supplemental oxygen but who are not mechanically ventilated or on extracorporeal membrane oxygenation (ECMO) if **remdesivir** supplies are limited.
  - Remdesivir recommendations were also revised, officially recommending remdesivir for 5 days or until hospital discharge in patients on supplemental oxygen (not on high flow oxygen or mechanical ventilation or ECMO). They make NO recommendation for patients on higher levels of oxygen or respiratory support, given the uncertainty of the data to support efficacy in this population.

Chloroquine/Hydroxychloroquine (CQ/HCQ)

- Two recent randomized controlled trials, one from Spain and the other from Brazil, cast further doubt on effectiveness of HCQ with or without azithromycin in mild to moderate COVID
- A three-arm, recent randomized, multi-center, open-label trial from Brazil in hospitalized patients with mild-moderate COVID-19 compared standard care alone to standard care + HCQ or standard care + HCQ and azithromycin (each for 7 days). Primary outcome was clinical status at 15 days based on an ordinal scale. There were also several secondary outcomes.
  - Just over 200 patients were randomized into each group (std. care n=229, HCQ n=221, HCQ+ azithro n=217). Mean age was 50 years and overall 58% were male. Many had underlying comorbidities and 42% required supplemental oxygen. Baseline characteristics were relatively well balanced between groups.
  - The Primary outcome at day 15 was not significantly different from those in the standard care group and either HCQ containing group. Results for sensitivity analyses were similar. There was also no significant difference in the number of patients requiring mechanical ventilation or who died.
  - Adverse events occurred in 23% of those on standard care, 34% of those on HCQ and 39% of those on HCQ + azithromycin
- The second trial from Spain was an open-label, randomized controlled trial in non-hospitalized patients with mild COVID-19 to HCQ or standard care. The primary outcome was reduction in viral load by days 3 and 7 and there were several other secondary outcomes.

- The primary population was the ITT sample – patients who were randomized and were PCR + for COVID19 (standard care n=157, HCQ n=136). The patients were largely healthcare workers and characteristics were similar between the two study arms. Mean age was 42 years, 69% were female and approximately half had underlying chronic conditions.
- There was no significant difference in reduction in viral load ag day 3 (- 1.41 log_{10} copies in each arm) or at day 7 (- 3.37 with standard care and – 3.44 HCQ)
- The risk of hospitalization was similar, at 7.1% for standard care vs. 5.9% with HCQ and median time to symptom resolution was also not different.
- Adverse events were documented in 9% of control patients vs. 72% of those receiving HCQ, most commonly gastrointestinal or nervous system related.

Remdesivir

- As noted above, the NIH/DHHS guidelines presented some recommendations on prioritization of remdesivir if supply was limited – focusing on the group shown to benefit the most in the NIAID trial, those requiring supplemental oxygen but who were not on mechanical ventilation or ECMO.

Immunomodulators

- Roche and Genentech announced on 7/28 that tocilizumab did not meet its primary endpoint of improved clinical status in hospitalized patients with severe COVID-19 pneumonia (COVACTA trial).
  - Difference in clinical status (using 7 point ordinal scale) at week 4 was not statistically different (OR 1.19, 95% CI 0.81 to 1.76, p=0.36).
  - Mortality at week 4 was 19.7% with tocilizumab vs. 19.4% with placebo.
  - Time to hospital discharge was shorter with tocilizumab (28 vs. 28 days) but statistical significance was not met as the primary endpoint was not met.
  - There was no significant difference in ventilator free days or infections at week four (38% vs. 41%) or serious infections (21% vs. 26%)
- This data is similar to the recently stopped randomized phase 3 trials for sarilumab, which also failed to show a difference
- These data contrast numerous retrospective, observational cohort studies, often with historical controls that showed potential benefit of IL-6 inhibitors on a variety of endpoints. Nonetheless, the study design of the randomized controlled trials is the stronger data, and do not support significant benefit at this time. It is unclear if recommendations will change based on the most recent phase 3 results, but clinicians should consider this data as they make decisions in hospitalized patients with severe COVID-19.

Vaccines

- Over 100 vaccines for COVID-19 are in clinical or pre-clinical development. Several recent studies have shown some of these vaccines to result in significant antibody levels, neutralizing antibodies, and T-cell responses

7/29/20

Guidelines, Clinical Recommendations and Other Important links on Treatment of COVID-19

- **Separate treatment guidance from the CDC, IDSA and NIH/DHHS note the limited evidence to support investigational and off-label therapeutics for treatment of COVID-19, and recommend that these treatments be studied in well-designed controlled clinical trials whenever possible. The DHHS panel acknowledges, however that many patients and providers may be seeking guidance and may not have access to clinical trials.**[1,2,3]
  - NIH COVID-19 Treatment Guidelines[2]
  - Interim Clinical Guidance for Management of Patient with confirmed COVID-19[1]: Centers for Disease Control and Prevention (CDC)
  - Guidelines from the Infectious Diseases Society of America[3] published April 11, 2020 - last updated 6/25/20

- The FDA released a drug safety communication on 4/21/20 cautioning against the use of CQ or HCQ in the outpatient setting and recommend they only be used for the treatment of COVID-19 in the setting of a clinical trial or in hospitalized patients per the FDA 3/28/20 Emergency Use Authorization for CQ or HCQ for COVID-19. On June 15th, in light of additional data on adverse events, and negative clinical efficacy, the FDA revoked the EUA, citing criteria were no longer met to warrant it.

- An expert CHEST consensus panel has developed guidelines for the prevention, diagnosis and treatment of venous thromboembolism in COVID-19.[4] This set of guidelines adds to additional updates in the NIH DHHS COVID-19 Guidelines[2], as well as those from the American Society of Hematology[5] and the Anticoagulation Forum Group[6].

- The FDA released an Emergency Use Authorization for use of remdesivir in hospitalized patients with severe COVID-19 infections in the U.S. on 5/1/20.

- In the absence of a clinical trial, any decision to consider off-label therapies in VHA be in keeping with the PBM Document entitled: Pharmaceutical Use Outside of Approved Indications Guidance on "Off-Label" Prescribing (August 2013). Decisions should be in consultation with facility experts, customized to the needs of the patient and carefully considering potential benefits and harms. Discussion of these risks/benefits should be clearly communicated to the patient and/or family as part of the decision prior to proceeding with off-label therapy.

- Please note this information is changing very rapidly and should be considered as updated as the current date of the document

Investigational and Off-Label Therapies under Evaluation for Treatment of COVID-19

REMDESIVIR: *Granted an Emergency Use Authorization (EUA) by the FDA on 5/1/2020 for treatment of hospitalized patients with severe COVID-19 (e.g. those requiring supplemental oxygen, mechanical ventilation or extracorporeal membrane oxygenation (ECMO), or those with a room air oxygen saturation ≤94%). Gilead is donating their initial supply of medication to the Federal Government and the distribution is being coordinated through AmerisourceBergen. Additional documents prepared by the FDA include a Fact Sheet for Patients and Caregivers, and a Fact Sheet for Health Care Providers (in place of traditional prescribing information).*

- Nucleotide prodrug antiviral with broad activity against several families of viruses, including the coronaviruses that cause Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome MERS [7,8,9,10,11] Animal data as both prophylaxis and treatment of MERS showed positive results[9]
- Completed early clinical trials for Ebola, including pharmacokinetic and limited safety data but was less effective than other treatment options
- Good in vitro activity against COVID-19[7]
- **Clinical trials ongoing in the U.S. for hospitalized patients with COVID-19:**
    - **Compassionate use administration** (see table 1) in hospitalized patients: improvement was 68%, mortality 13% and 47% had been discharged at the date of their last follow-up[12]
    - **Randomized, placebo-controlled trial in China** halted prematurely when epidemic controlled, making further recruitment difficult[13]
        - Underpowered for primary endpoint but did not show significant difference in time to clinical improvement, mortality, time to reduction of viral load or other secondary clinical endpoints, although positive trends seen in some cases
        - No significant safety signals other than rash (7% vs. 3% and thrombocytopenia 10% vs. 6%)
    - **Results of NIAID ACTT-1 Trial** of 1063 hospitalized patients with COVID-19 found remdesivir superior to placebo in time to clinical recovery: 11 days vs. 15 days (rate ratio for recovery 1.32, 95% CI 1.12 to 1.55, p<0.001) and trend towards decreased mortality: 7.1% vs. 11.9% (HR for death 0.7, 95% CI 0.47 to 1.04, p=0.059)[14]. All patients were treated for 10 days. These data led to the FDA EUA of remdesivir.
        - The benefit was statistically significant only in the group of patients who required supplemental oxygen at baseline, but not in those who were less ill, or those requiring invasive or non-invasive mechanical ventilation, suggesting the group most likely to benefit from treatment with remdesivir in addition to standard care
        - The FDA EUA suggests patients who are not severely ill could be considered for treatment with 5 days of therapy, to be extended if they do not show clinical improvement, based on topline results from the SIMPLE trial that did not show a difference in clinical improvement with 10 vs. 5 days of remdesivir in severe COVID-19), but without a control group, it is unclear exactly what efficacy remdesivir holds in severely ill patients.[15] Another press release from 6/1/20 included topline results from the phase 3 SIMPLE trial of moderately ill patients, which included a standard of care arm. In this study – 5 days but not 10 days, was associated with improvement in ordinal score at day 11 versus standard of care. This supports the shorter treatment duration in moderately ill patients.
        - Most common adverse events included increased transaminases, rash, diarrhea, renal impairment and hypotension.
    - A press release by Gilead on 7/10/20, of data presented at the International AIDS Conference compared the Phase 3 SIMPLE severe cohort patients with a real-world retrospective cohort, and in this analysis, remdesivir was associated with a 62% reduction in mortality. In this cohort, 312 patients who received remdesivir were compared with 818 patients with similar baseline characteristics. The mortality rate for patients treated with remdesivir in the analysis was

7.6 percent at Day 14 compared with 12.5 percent among patients not taking remdesivir (adjusted odds ratio 0.38, 95% confidence interval 0.22-0.68, p=0.001). Clinical recovery by day 14 occurred in 74% of remdesivir and 59% of control patients.
    - They also provided information about subgroups of traditionally marginalized racial and ethnic subgroups had similar outcomes to the overall cohort.
  - Dose is 200mg IV once followed by 100mg IV daily. The FDA EUA suggests 5 days of therapy for those not requiring mechanical ventilation (with the option to extend up to 5 additional days for patients who do not respond) and 10 days of therapy for those on mechanical ventilation or ECMO
  - Uncontrolled safety data from phase 1 trials and compassionate use data for treatment of Ebola primarily demonstrated reversible grade 1 and 2 elevations of AST or ALT.[16] In the ACTT trial, serious adverse events occurred in 21% of remdesivir and 27% of placebo patients with only 2 reactions in each group felt to be study related.[11] Most adverse events were not significantly different from placebo, including acute kidney injury (0.7% remdesivir vs. 1.3% placebo) or increased transaminases (0.6% vs. 1.1%). Hypotension was recorded in 2.2% of those receiving remdesivir and 1.3% of patients receiving placebo
- **SAFETY**
  - Overall, remdesivir appears to be well tolerated, based on results from randomized trials, however, two recent updates are notable. Gilead reported a drug-drug interaction between remdesivir and hydroxychloroquine, suggesting the effectiveness of remdesivir may be diminished when co-administered with hydroxychloroquine, resulting in an FDA safety alert.
  - Elevations in liver enzymes were noted during the Ebola trial, but did not appear to be greater than placebo in the ACTT-1 trial. Of note, patients with significant renal dysfunction were excluded. A recent case report of a patient who received amiodarone with remdesivir and developed transaminase elevations > 1000 U/mL, which decreased rapidly when remdesivir was discontinued.[17] The authors suggested an interaction due to the p-GP inhibition of amiodarone, potentially resulting in elevated levels of remdesivir.

CHLOROQUINE / HYDROXYCHLOROQUINE (CQ/HCQ)

- Antimalarial drugs with nonspecific activity against several coronaviruses, including in vitro activity vs. COVID-19.[18,19] An Emergency Use Authorization (EUA) was issued by the FDA for the use of CQ or HCQ as treatment for COVID-19 infections on 3/28/20 subject to specific criteria and when issued by a valid prescription. A recent FDA Safety briefing cautions against the use of HCQ or CQ outside of a clinical trial or hospital setting due to arrhythmia risk . The NIH Treatment Guidelines were updated on 6/11/20 and now recommend AGAINST the use of HCQ or CQ except in the context of a clinical trial and recommend against high dose CQ or the combination of HCQ and azithromycin due to toxicity and on **June 15th, the FDA revoked the EUA** citing limited clinical data on effectiveness, but significant risk of cardiac and other adverse events.
- ***Data on use of HCQ or CQ as treatment of COVID-19 does not support significant efficacy for treatment or prophylaxis of COVID-19 (Table 1). Emerging data regarding cardiac involvement with COVID-19 requires caution with use of CQ and HCQ, and close monitoring of QTc if used (see table 3). Both the NIH and the IDSA COVID-19 guidelines do not recommend either HCQ or HCQ with azithromycin outside of the context of a clinical trial.***[2,3]
  - Recent randomized, controlled trials provide higher quality evidence to assess the safety and efficacy of HCQ or CQ for the treatment or prophylaxis of COVID-19 infections. Prior to this data was limited to retrospective cohort studies, which suffered from serious bias, limiting confidence in their findings. Nonetheless, the majority of retrospective studies evaluating the impact CQ/HCQ on virologic outcomes were not able to demonstrate a reduction in time to negative viral PCR for COVID-19.[20,21,22,23,31] In addition, only 1 small randomized trial demonstrated HCQ associated with 1 day less of fever and cough while the other trials did not find a difference in clinical outcomes between those who received CQ/HCQ vs. standard care.[16,17,18,24,25,26,27] The retrospective cohort studies with propensity score adjustments did not find association between HCQ and risk of progression to mechanical ventilation/intubation, or a composite of intubation or death. One study did find an increased risk of death from any cause in patients who received HCQ but should be viewed as preliminary.[19-22]

Another noted a decreased hazard ratio for in hospital mortality with either HCQ or HCQ + azithromycin but numerous difference in baseline characteristics bring in concern for residual confounding.[28]

- **Randomized clinical trials**
  - **Treatment:**
    - Two early randomized trials from China, one with 150 patients, the other with 62 patients did not showed marked advantage of HCQ on efficacy outcomes, other than 1 day shorter duration of fever and cough in the smaller trial.[20,22]
    - More recently, two large randomized controlled trials, one from Spain and the other from Brazil failed to show a difference in clinical endpoints as treatment for COVID-19.[29,30]
      - The first, from Spain, evaluated 293 patients with mild COVID-19 (outpatients) who were randomized to HCQ for 7 days or standard care.[29] At both 3 and 7 days, there was no difference between groups in reduction of COVID-19 viral load. In addition, HCQ did not decrease the risk of hospitalization or shorten time to complete symptom resolution.
      - In the other large trial, patients hospitalized with mild-to-moderate COVID-19 (not requiring high levels of oxygen or ventilatory support) were randomized to 1 of 3 groups: standard care alone, standard care with HCQ or standard care with HCQ + azithromycin.[30] Neither HCQ or CQ were associated with improved clinical outcomes, according to a 7 point ordinal scale
  - **Prophylaxis:** a large, randomized, placebo controlled trial in over 800 patients with high risk exposure to COVID-19 (occupational or household contact) failed to show benefit but was associated with significantly more adverse events.[31] In this trial, participants were given 5 days of HCQ who were enrolled within 3-4 days after exposure. Of the 414 patients who received HCQ, 11.8% developed COVID-19 compatible illness, compared with 14.3% of 407 placebo patients. Adverse events were significantly more common with HCQ, especially nausea (23% vs. 8%), and diarrhea/abdominal pain/vomiting (23% vs. 4%)
- **Safety / adverse events:**
  - While generally well tolerated when used as malaria prophylaxis (CQ/HCQ) or chronically for rheumatoid arthritis or lupus (HCQ), do have a narrow therapeutic index with 6 grams being a fatal dose in an adult. HCQ is generally felt to be safer than CQ. Patients with COVID-19 may have additional risk factors, such as myocardial involvement of COVID-19, electrolyte disturbances, and other medications that may increase risk of adverse events to CQ/HCQ.
    - QT prolongation with QTc ≥ 10-35% in several case series, including rare cases of ventricular arrhythmia [32,33,34,35,36]
    - Appears dose dependent and greater when combined with azithromycin, and cardiovascular manifestations of COVID-19 may contribute to the risk
    - All patients should have an EKG prior to administration of HCQ and CQ and during therapy to assess effect of the medication.
  - In the randomized controlled trial from Spain, 72% of patients receiving HCQ developed any AE vs. only 9% of the standard care groups. Differences in gastrointestinal (diarrhea, abdominal pain) and neurologic symptoms (headache, metallic taste) were the most common side effects.
  - **Other side effects to monitor include** rash - a case of drug reaction with eosinophilia and systemic symptoms- DRESS, and one severe exacerbation of psoriasis have been reported, central nervous system (seizures), gastrointestinal and hematologic effects (hemolytic anemia), weakness, and hypoglycemia
  - Both can inhibit CYP2D6 and result in drug interactions with other common medications so this should be checked also prior to initiation (e.g. beta-blockers)

Lopinavir/ritonavir (Lop/rit)

- Commercially available antiviral for the treatment of HIV with In vitro activity against several coronaviruses, including SARS, MERS and COVID-19
- **Early in China, many patients treated empirically with lop/rit, but efficacy data is lacking and best evidence does not support use in patients with severe COVID**

- Data from the first randomized controlled trial of lop/rit vs. control in 199 patients with severe COVID for 14 days did not show benefit in reducing time to clinical improvement or negative viral PCR for COVID and was associated with an increased risk of gastric adverse events[37]
- **Recent study of combination of Lop/rit + ribavirin and interferon beta-1b vs. Lop/rit alone** in patients with mild/moderate COVID-19 suggested some benefit on clinical and virologic outcomes, but given known side effect profile of interferons and ribavirin and very rapid results demonstrated, role of this therapy remains to be defined further[38]

- **Doses have ranged from 400mg/100mg to 400mg/200mg twice daily of lop/rit**
  - Note crushing of tablet may reduce bioavailability by 50%[39]
- **Gastrointestinal tolerance** may be a significant issue – in one report of use in 5 patients with COVID-19, nausea, vomiting or diarrhea developed in 4 of 5 and increased liver enzymes in 3 of 5 although causality unclear
- **Drug-drug interactions are common with lop/rit, including medications that are contraindicated. Like HCQ/CQ and azithromycin, lop/rit can prolong the QTc. A pharmacist should review the patient's medication list for drug interactions and necessary adjustments prior to initiation**

Darunavir +/- ritonavir or cobicistat (DRV/r, DRV/c)[40]

- Press release on J&J.com states Janssen has NO clinical NOR pharmacological evidence to support inclusion of DRV/cobicistat in treatment guidelines for COVID-19, nor are there published data on safety and efficacy of DRV, DRV/c or DRV/c/emtricitabine/tenofovir alafenamide for treatment of COVID-19
- **They also report – unpublished in vitro data suggest DRV is UNLIKELY TO HAVE SIGNIFICANT ACTIVITY VS. COVID-19 AT SAFE/EFFICACIOUS DOSES**
- **Finally, they refer to a single-center open-label randomized controlled trial from China of DRV/c in 30 patients that showed DRV/c was NOT EFFECTIVE**
- **Based on available evidence, DRV, DRV/c and DRV/r are NOT recommended to treat COVID-19 at this time**

Other agents studied as therapeutic agents in patients with severe COVID-19

IMMUNOMODULATORS – severe COVID-19 has been associated with cytokine storm or a cytokine release syndrome (CRS)-like pathology which manifests as rapid clinical deterioration and increased levels of CRP, ferritin, d-dimer, LDH and IL-6 along with fever and ARDS. Degree of CRS related to disease severity possibly mediated by fulminant immune response.

- **IL-6 Inhibitors** High IL-6 (and other inflammatory markers) has been associated with severe COVID-19 and increased risk of ARDS and mortality in some retrospective analyses of COVID-19. A similar syndrome of CRS seen with CAR T-cell therapy in oncology has been successfully treated with tocilizumab and it holds an FDA indication for CRS associated with CAR T-cell therapy.[42] The IL-6 inhibitors are anti-IL-6 monoclonal antibodies that bind to IL-6, with an intent to mitigate the ongoing immune response in CRS.
  - IL-6 inhibitors currently being investigated in randomized controlled trials
  - Patients with low platelets or neutrophil counts, elevated AST/ALT, or active infections are generally excluded from ongoing clinical trials.
  - Most current data are small, single center case series without a control arm, making it difficult to draw conclusions regarding the impact and potential efficacy on clinical outcomes. Ongoing clinical trials should be forthcoming, but for now this data is extremely preliminary and must be considered in the context of potential risks vs. benefits.
  - **As of the update on 6/11/20, the NIH/DHHS guidelines say there is insufficient evidence to recommend for or against these agents at this time.**
  - **Additional information on each agent can be found below and in table 1.**

- **Tocilizumab (TOCI)**[41]
  - **Data to support tocilizumab are primarily case reports or small, single-center, open-label case series of tocilizumab without a control group, using inflammatory markers (e.g. CRP) as the primary endpoints along with clinical descriptive endpoints.**
    - Most case series included patients with severe COVID-19 infection, and evidence of hyperinflammation through laboratory markers (CRP, ferritin, IL-6, LDH) as per local or regional protocols.[42,43,44,45] Patients were generally given 1-2 doses over 1-3 days. In all of these series, some markers, especially fever and CRP, decline rapidly after infusion (within 7 days) often as part of institutional protocol. Clinical endpoints are difficult to interpret without a control group. In nearly all series patients were also on several other COVID-19 therapies (HCQ or CQ, lop/rit, corticosteroids).
    - Several case series attempted to compare TOCI with historical control groups.[46,47,48,49,50,51] Unfortunately, these are small and the populations may not be well matched at baseline, and unclear how well statistical adjustment can control for confounding variables. Given rapidity of improvements in care of COVID-19 patients (e.g. prone positioning), historical time bias may also be a factor. Some did find improvements in clinical outcomes, such as lower progression to ICU care or mortality, while others did not.
    - **Press release from Roche** released top-line results from **CORIMUNO-TOCI** trial, where 129 patients with moderate or severe COVID-19 were randomized – 65 to standard care + tocilizumab and 64 to standard care alone, and a significantly lower proportion of patients in the tocilizumab arm met the composite endpoint (need for invasive or non-invasive ventilation or death at day 14).[47] Full published results are not available.
    - **Safety:** with long-term use of IL-6 inhibitors for rheumatoid arthritis, an increased risk of severe and opportunistic infections, neutropenia, thrombocytopenia, elevated transaminases and rare gastrointestinal perforation are described. Unclear what risk short treatment course in a different population would entail, and adverse events difficult to interpret in absence of control group. One series did identify
      - **Adverse events in case series of tocilizumab for COVID-19** reported in 0-92% of patients. Reported adverse events include hepatic cytolysis and ventilator associated pneumonia in one series, hypertriglyceridemia and pancreatitis, reactivation of herpes simplex and *Candida* isolation from respiratory tract, anemia, QT prolongation, bacterial superinfection and acute kidney injury, although given the lack of a control group, degree of illness of the patients, and numerous other therapies received, attribution to tocilizumab is not clear.
      - **Looking at data from matched cohort studies of TOCI vs. standard care on rates of infectious complications**
        - **Guaraldi et al.** new infections in 13% TOCI vs. 4% standard care, including one case of fatal HSV reactivation
        - **Somers et al.** new superinfections in 54% TOCI vs. 26% standard care, mostly pneumonia, which was not associated with worse mortality
        - **Rissotti et al.** 27 infections in 24 patients (32%) who received TOCI, including gram-negative sepsis, gram-positive sepsis, candidemia, a lung abscess and an epidural abscess. Not reported for standard care patients
        - **Kimming et al (University of Chicago)**: compared infections in patients who received TOCI vs. those who did not. TOCI was associated with more bacterial (50% vs. 29%) and fungal (8% vs. 0%) superinfections[52]
- **Sarilumab (SARI)**
  - **Currently no published data to support sarilumab as treatment for COVID-19 associated CRS.**
  - A press release from Regeneron on 4/27/20 provided an update on the ongoing Phase 2/3 adaptive trial in hospitalized patients. This trial was comparing high dose sarilumab (400mg), low dose sarilumab (200mg) and placebo as an **INTRAVENOUS** single infusion, in two groups of patients – those with severe illness and those with critical illness. An analysis of the Phase 2 randomized data showed rapid reductions in CRP in all treatment arms, but in exploratory clinical outcomes, **no notable benefit was seen in the combined groups**. When separated, there were negative trends for most outcomes in the severe illness group and positive trends in the critical illness group. As a result of this, the severe illness arm was dropped from the Phase 3 trial and only patients who are critically ill will be continued.

- When discontinued, patients from the severe arm of the phase 3 study were examined, and the trends did not appear to be seen.
- An additional press release on July 2nd from Regeneron stated that the Phase 3 trial was stopped after a subsequent analysis showed that the 400mg dose in critically ill patients did not meet its primary or secondary endpoints. In addition, adverse events were experienced by 80% of Kevzara patients and 77% of placebo patients. Serious adverse events that occurred in at least 3% of patients and more frequently among Kevzara patients were multi-organ dysfunction syndrome (6% Kevzara, 5% placebo) and hypotension (4% Kevzara, 3% placebo).
- This is consistent with a retrospective cohort study from Italy which did not show a significant difference in clinical improvement versus standard care alone.[53] Infections, elevated liver enzymes and neutropenia were the most commonly reported adverse events.

- **Siltuximab (SILTUX)**
  - IL-6 inhibitor indicated for treatment of multicentric Castleman's disease
  - Small case series of 21 patients from Italy with ARDS on noninvasive mechanical ventilation or CPAP (with elevated CRP and IL-6 levels) described as a preprint – 11 mg/kg IV as a single infusion (5/21 received 2nd dose for inadequate response).[54] No control group was available.
    - CRP normalized by day 5 and remained stable in all 16 patients with available data. Clinical improvement noted in 33% (no longer requiring CPAP or NIVV) -worsening in 24%, 1 intubation and one cerebrovascular accident. No other clinical or laboratory data available

- **IL-1 inhibitor: Anakinra**
  - Anakinra inhibits IL-1 activity by competitively binding to IL-1 receptor used to treat auto-inflammatory disorders (e.g. familial Mediterranean fever)
  - IL-1 produced in high levels by macrophages during hyper-inflammation and inhibition of IL-1 activity postulated to also potentially have benefit in treating patients with CRS associated with COVID-19.
  - Current data limited to case reports and small case series but several studies ongoing
    - One retrospective case series from Italy included patients with COVID-19 and ARDS managed outside ICU on non-invasive ventilation (all also received HCQ and lop/rit).[55] Most patients (n=29) received high-dose intravenous anakinra (5 mg/kg IV twice daily over 1 hour) for at least 2 days or until a 75% reduction in CRP and improved respiratory function or until side effects arose, followed by low-dose subcutaneous (SQ) administration if improved. A small number received ONLY low-dose 100 mg SQ twice daily (n=7). A comparison group was patients admitted prior to study initiation who would have met criteria for anakinra (n=16). Groups were fairly well matched other than slightly higher CRP and ferritin in the comparator group, and more patients with severe ARDS in the high-dose anakinra group (no statistics given re: comparison)
    - By Day 21 – 45% of high-dose anakinra patients had been discharged vs. 44% with standard therapy. Mechanical ventilation at day 21 was seen in 17% of anakinra vs. 6% of comparator and death occurred in 10% vs. 44% (p=0.009). Given the small numbers and lack of statistical adjustment for confounders, this study should be confirmed by larger trials
    - **Safety**: treatment was discontinued for adverse events in 24% of patients after a median of 9 days – 14% due to bacteremia and 10% due to increases in serum liver enzymes (although similar outcomes occurred in the comparator group as well)

- **JAK/NAK inhibitors baracitinib, ruloxitinib, tofacitanib[56]**
  - Numb associated kinase (NAK) inhibitor suggested in AI modeling as possible therapy but data limited to case series and further studies ongoing
  - Concerns about increased risk of thrombosis have been raised, given drug warnings, and a series of 2 patients with severe dermatologic reactions has been described
  - Recent NIH sponsored ACTT trial adapted to change placebo arm to combination of remdesivir + baracitinib (vs. remdesivir alone)

- **Eculizumab**
  - Human monoclonal antibody that binds complement protein C5 and inhibits complement activation
  - Ongoing expanded access study for severe COVID-19
  - Very small case series from Italy – in patients with severe COVID-19 requiring hospitalization, bilateral pneumonia on imaging, requiring oxygen supplementation.[57] Patients received 900mg IV over 35 minutes weekly for up to 4 weekly doses. All received LMWH, lop/rit, HCQ, **ceftriaxone 2g IV daily,** ascorbic acid 6 grams/ day for 4 days, CPAP. Four patients (2 males, 2 females) aged 53-82 admitted to sub-ICU with illness duration 13-18 days, and elevated PT, d-dimer, CRP. All received a total of 2 doses, with rapid decline in CRP (by 48 hrs in all patients). Improvement in chest CT findings was also described and duration of illness ranging from 13-18 days. No mention made of vaccination against meningococcus, and although all patients received ceftriaxone, no specific mention of prophylaxis during therapy
  - **Safety:** eculizumab associated with **severe meningococcal infections** requiring vaccination and prophylaxis

- **Corticosteroids**
  - The Infectious Diseases Society of America (IDSA) and NIH/DHHS both updated their COVID-19 Treatment guidelines on 6/25/20 based on the results of the **RECOVERY** trial.[58] Data from an interim analysis of the RECOVERY trial in the United Kingdom resulted in the halting of the dexamethasone arm of the trial on June 8th, as sufficient patients had been enrolled to establish a meaningful benefit.
    - Of the 2104 patients randomized to receive dexamethasone 6 mg once daily for 10 days, dexamethasone reduced deaths by 1/3rd in ventilated patients (rate ratio 0.65, 95% CI 0.48 to 0.88) and by 1/5th in other patients receiving oxygen (rate ratio 0.80, 95% CI 0.67 to 0.96). No benefit was seen among patients not requiring respiratory support (rate ratio 1.22, 95% CI 0.86 to 1.75).
  - Both guidelines recommend (NIH) or suggest (IDSA) dexamethasone 6 mg daily for up to 10 days in patients who are mechanically ventilated or require supplemental oxygen and recommend (NIH) or suggest (IDSA) against it for those not requiring supplemental oxygen.
    - For situations where dexamethasone is unavailable, the IDSA guidelines suggest alternative corticosteroids at an equivalent dose (e.g. methylprednisolone 32mg or prednisone 40mg or hydrocortisone 160mg) may be an alternative
    - The NIH guidelines acknowledge the limitations of data to support other corticosteroids in COVID-19
    - The VA Evidence Synthesis Program updated their Rapid Review on 6/26/20 with a summary of RECOVERY and observational studies of corticosteroids for treatment of COVID-19
  - Most available data comes from case series and cohort studies, often with a historical control, and suffer from potential indication bias as patients who are treated with steroids are likely to be different from those who are not. A short summary of additional observational data are listed below.
    - **Positive studies:**
      - A retrospective cohort from China of 46 patients with severe COVID-19, 26 of whom received methylprednisolone 1-2 mg/kg/d x 5-7 days.[59] Patients on methylprednisolone had a faster improvement in SpO2, a shorter duration of supplemental oxygen (8 vs. 14 days) and were less likely to end up on the ventilator (12% vs. 35%). *It wasn't clear why some received steroids and others didn't. The groups were fairly well matched, although no mention of adjustment for potential confounders was made*
      - A pre-post quasi experimental study of 213 patients at Henry Ford Hospital (a pre-post) with moderate to severe COVID-19 after implementation of an early steroid protocol.[60] They found that early methylprednisolone 0.5 – 1 mg/kg/day x 3 days was associated a

decrease in the composite endpoint of transfer to the ICU, intubation or death – 35% vs. 54% (and each outcome separately). Length of stay was also shorter. Some of the control group got later steroids at their physicians' discretion (57%) and not all of the early corticosteroid group got steroids (only 68%) but more were started within 48 hours of presentation (median of time to initiation of 2 vs. 5 days). *The groups were not randomized, and there was potentially a time bias. It does appear a change may have been made related to prone positioning.*

- A retrospective cohort of 201 patients in Wuhan with COVID-19 to identify risk factors for development of ARDS and death.[61] 42% developed ARDS and in that subgroup, methylprednisolone was associated with a reduced risk of mortality (HR, 0.38, 95% CI 0.20 to 0.72). While an interesting finding, it was a subgroup analysis with potential bias and confounding

- **Negative studies:**
  - A retrospective cohort of 132 patients with non-severe COVID-19 pneumonia.[62] Propensity score matching was used to adjust for baseline differences between steroid and non-steroid groups and were used to create 35 pairs. The dose of methylprednisolone was largely 40-50 mg for a median of 11 days. Progression to severe disease was more common in the corticosteroid group (11% vs. 3%), with no significant differences on hospital length of stay, duration of viral shedding or fever.
  - A letter to the editor describing a retrospective cohort of 244 patients compared patients who received steroids and those who didn't, using propensity score matching to adjust for differences.[63] Despite matching, patients who received steroids had more ARDS, septic shock, MI, AKI, DIC and liver injury, although these were not statistically different (only compared 31 pairs). Corticosteroids were not associated with a significant increase in mortality (39% vs. 16%, p= 0.09), but they did find that higher doses of steroids were significantly associated with mortality risk after adjusting for administration duration.
- A large international registry of patients with inflammatory bowel disease evaluated 525 patients from 33 countries to see if specific factors were associated with severe COVID-19.[64] Besides age and comorbidities, corticosteroids were associated with increased risk of severe disease (aOR 6.9, 95% CI 2.3 to 20.5), as was sulfasalazine, while TNF antagonists were not associated with increased risk. *As a retrospective registry, these populations are likely different, which may account for some of the differences, despite statistical adjustments to address confounding*
- **2 cohort studies found steroids were associated with an increased time to viral clearance** or increased duration of viral detection.

- Another supportive RCT that just came out of dexamethasone in ARDS (not-COVID-19 related), which also supports the findings although the dosing was different in that trial.[65] It was stopped early (after 88% had been enrolled) due to low enrollment (n=277). They found a higher number of ventilator free days (difference of 4.8 days) and at 60 days mortality was 21% (dexamethasone) vs. 37% (control) It's possible it is something specific to dexamethasone. The majority of the above cohorts used methylprednisolone at various doses.
- **Drugs hypothesized to cause harm in patients with COVID-19 and available data to support / refute**
  - **Nonsteroidal anti-inflammatory agents (NSAIDs)**
    - In March 2020, the French minister of health recommended avoiding NSAIDs and using paracetamol (acetaminophen) for fever after an infectious diseases physician in France cited 4 cases of young healthy patients who developed severe COVID-19 after using NSAIDs in the early stages of disease
    - Editorial published in BMJ laid out a case for possible harm based on observational studies in respiratory tract infections finding NSAIDs associated with increased risk for complications.[66]
    - Others have rebutted this as likely confounded by indication and disease severity[67]
    - **Currently the CDC, the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA) all state there currently is no data to support that NSAIDs are associated with worse clinical outcomes in COVID-19, although the FDA and EMA continue to monitor the situation[68,69]**
  - **Angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB) or other renin angiotensin aldosterone antagonists (RAAS)**

- Hypotheses both of possible benefit and of harm with renin angiotensin blockers (ACE/ARB) and studies are ongoing both to assess impact of these drugs in patients with COVID-19 who are on the medications for another indication. In addition, clinical trials of ACE inhibitors and ARBs as a therapeutic intervention in COVID-19 are registered in Clinicaltrials.gov
- **The American College of Cardiology, American Heart Association and Heart Failure Association of America released a joint statement on 3/17/20 stating there was no data to demonstrate either a beneficial or adverse outcome with the use of ACE inhibitors, ARBs or other RAAS antagonists in COVID-19 patients and recommended continuation of therapy in those patients who were prescribed these drugs for indications where they are known to be beneficial, such as heart failure, hypertension and ischemic heart disease. They also recommended these drugs not be added beyond standard indications.[70]**
    - A recent meta-analysis of 14 articles involving more than 19,000 patients with COVID-19 did not find use of ACEI or ARBs was associated with a higher risk of COVID-19 infection (OR 0.99; 95% CI 0.95, 1.04), higher severity of infection (OR 0.98; 95% CI 0.87, 1.09) or mortality (OR 0.73; 95% CI 0.5, 1.07) vs. those not taking an ACEI or ARB prior to COVID-19 infection. In contrast, for those patients on antihypertensive medication prior to COVID-19, those with ACEI/ARB exposure had a lower risk of mortality, than non-ACEI/ARB antihypertensives (OR 0.48; 95% CI 0.29, 0.81) p=0.006[71]

See Tables 1-3 for additional information on primary potential therapies for COVID-19 Appendix 1 has information related to additional agents currently being investigated but with no clinical data.

Table 1: Data on Off-label Pharmacotherapeutics studied for potential activity vs. COVID-19

Medication	Study Design	Demographics/results	Outcomes/Comments
Remdesivir (GS-5734) – investigational antiviral with activity against a broad range of coronaviruses. Functions as a nucleotide analog, resulting in viral chain termination. **Has completed phase 1 trials (Safety, tolerability and pharmacokinetics) as well as data from compassionate use for Ebola virus infections in 2014** ***Additional ongoing trials in China and other countries***			
Wang et al.[8] **Remdesivir in adults with severe COVID-19: randomized, double-blind study in China**	Investigator-initiated, randomized placebo-controlled, trial of intravenous remdesivir in Wuhan (2:1 randomization) **Inclusion:** Adults PCR positive for COVID-19 Pneumonia on chest imaging O2 sat ≤94% on room air or PaO2 ≤ 300 mmHg **Exclusion:** Pregnancy/lactation Cirrhosis or AST/ALT > 5 X ULN eGFR < 30 mL/min/1.73 m^2 **Dose:** 200mg IV on day 1 then 100mg IV on days 2-10 or placebo **Primary endpoint:** Time to clinical improvement within 28 days after randomization (2 point reduction on 6 point ordinal scale or live discharge *with NEWS 1 being discharged from hospital not requiring oxygen to NEWS 6 death)*	**ITT population:** planned to enroll 453 patients but due to decreasing cases in Wuhan, study was stopped for difficulty to enroll further **Remdesivir n=158** / **Placebo n=78** **Age** 66 yrs / 64 yrs **% male** 56% / 65% **Hypertension** 46% / 38% **Diabetes** 25% / 21% **Coronary disease** 9% / 3% **NEWS 3** 82% / 83% **Time from symptoms** 11 days / 10 days **IFN α-2b** 29% / 38% **Lopinavir/rit** 28% / 29% **Vasopressors** 16% / 17% **Corticosteroids** 65% / 68% **Non-inv. Ventilation** 9% / 4% **Invasive ventilation** 7% / 13%	**Results:** **Primary outcome: Time to clinical improvement** Remdesivir: 21 days Placebo: 23 days Difference 1.23 (95% CI 0.87 to 1.75) **Secondary outcomes:** **28 day mortality** Remdesivir: 14% Placebo: 13% Difference 1.1% (95% CI -8.1% to 10.3%) *If given EARLY (within 10 days of symptom onset)* *Mortality was 11% vs. 15% (Rem vs. placebo)* *If given LATE – mortality was 14% vs. 10%* Duration of mechanical ventilation Remdesivir 7 days Placebo 15.5 days Diff -4.0 (95% CI -14.0 to 2.0) Duration of oxygen support – 19 vs. 21 days Duration of hospital stay – 25 vs. 24 days
Beigel et al.[14] **Remdesivir vs. placebo for patients with severe COVID-19 (ACTT)**	NIAID sponsored randomized, placebo-controlled trial of hospitalized patients with COVID-19 and one of the following 1. Radiographic evidence 2. Oxygen sat ≤ 94% on room air OR 3. Requiring supplemental oxygen, or mechanical ventilation Dose 200mgx1, followed by 100mg dailyx9 days *Patients with eGFR < 30 mL/min, pregnancy or severe elevation AST/ALT excluded* Primary outcome: Time to clinical recovery (TTCR) based on 7 point ordinal scale	**Study cohort included 541 patients randomized to remdesivir and 522 to placebo** **Demographics:** Mean age 59 yrs in both groups 65% and 64% were male 53% remdesivir and 52% placebo pts had 2 or more comorbid conditions **Severity of illness (remdesivir vs. placebo)** 4 (hospitalized, not requiring oxygen) 12.4% vs. 11.5% 5 (hospitalized, requiring oxygen): 41% vs. 38% 6 (hospitalized requiring noninvasive ventilation or high flow nasal oxygen (18% vs. 19%) 7 (mechanical ventilation/ECMO) 23% vs. 28%	**Results:** Median time to recovery 11 days with remdesivir vs. 15 days with placebo with rate ratio for recovery 1.32 (95% CI 1.12-1.55), p<0.001. Benefit was primarily significant in patients hospitalized and requiring supplemental oxygen Mortality at 14 days: 7.1% remdesivir vs. 11.9% placebo (HR death 0.70, 95% CI 0.47 to 1.04) Patients who were on mechanical ventilation nor ECMO did not appear to have benefit, although these are subgroup analyses and should be hypothesis generating Adverse events were similar between remdesivir and placebo groups

Goldman et al. [12] **Remdesivir 5 vs. 10 days in severe COVID-19 (SIMPLE)**	Phase 3, open-label trial in hospitalized patients with severe COVID-19 randomized to 5 or 10 days of remdesivir. Inclusion: hospitalized with COVID-19 and 1. Radiographic evidence OR 2. Oxygen sat ≤ 94% on room air OR 3. Requiring supplemental oxygen *Patients on mechanical ventilation or ECMO, those with eGFR < 50 mL/min, or AST/ALT > 5 times normal were excluded* Dose 200mg x 1, followed by 100mg daily for 4 or 9 days Initial primary outcome: proportion of patients with normalization of fever and oxygen saturation by day 14, but changed to 7 point ordinal scale as above Safety outcome included adverse events	**Demographics (5 vs. 10 days, respectively)** Median age 61 vs. 62 yrs. Male sex: 60% vs. 68% Caucasian: 71% vs. 70% HTN 50% of each group, DM 24% and 22% Initial clinical score 3 (noninvasive ventilation/high flow nasal oxygen): 24% vs. 30% 4 (low flow supplemental oxygen): 56% vs. 54% 5 (not on supplemental oxygen): 17% vs. 11% Median duration of symptoms was 8 days in the 5 day and 9 days in the 10 day groups	**Outcomes:** Clinical status at day 14, 5 day vs. 10 days, respectively 1 (Death): 8% vs. 11% 2 (mechanical ventilation): 8% vs. 17% 3 (noninvasive ventilation): 4% vs. 5% 4 (low flow oxygen): 10% vs. 7% 5 (no oxygen but other ongoing care): 6% vs. 7% 6 (hospitalized but no oxygen or ongoing care): 4% vs. 2% **7 (Not hospitalized):** 60% vs 52% Median time to clinical improvement was 10 days vs. 11 days Adverse events in 70% of the 5 days group vs. 75% of the 10 day group – difficult to assess in absence of control group.
Chloroquine (CQ) / Hydroxychloroquine(HCQ) –antiviral agent with activity vs. several viruses, including coronaviruses, thought due to ability to create an alkaline environment which hampers pH dependent viral replication			
Mitja et al.[29] RCT of HCQ vs. standard care in outpatients with mild COVID-19	**Randomized, open-label multicenter trial in Spain of standard care vs. HCQ + standard care** Patients were non-hospitalized and within 5 days of symptom onset, without contraindications to HCQ. Primary outcome was reduction of viral RNA at days 3 and 7 along with several clinical secondary endpoints	**Baseline characteristics:** In the ITT population, 157 patients were assigned to standard care vs. 136 to HCQ. Mean age was 42 yrs, 69% were female and median time from symptom onset was 3 days. Chronic health conditions were reported in 53% of patients. Groups were well-balanced, without significant differences in baseline characteristics	**Results:** For the primary outcome, there was NO difference in reduction in viral load at day 3 (-1.41 log in both groups) or at day 7 (-3.37 log and -3.44 log with standard and HCQ respectively) Risk of hospitalization was similar between groups: 7.1% with usual care and 5.9% with HCQ. No patients required mechanical ventilation and none died. Time to resolution of symptoms also did not differ. Adverse events occurred in 9% of standard care vs. 72% of HCQ patients. Gastrointestinal and nervous system symptoms were most common.
Cavalcanti et al.[30] Randomized controlled trial of HC, HCQ+azithro or	**Randomized, open-label multicenter trial in Brazil of standard care, HCQ or HCQ+ azithromycin x 7 days in hospitalized patients with mild-moderate COVID-19**	**504 of 667 randomized patients had confirmed COVID-19 and made up the mITT population** Mean age of patients was 50 years, 58% were male. Supplemental oxygen at baseline was required in 42% of patients and most had one or more comorbidities.	**Results:** Among patients with confirmed COVID-19, there were no significant between-group differences in proportional odds of having a worse score on the 7 point ordinal scale.

standard care in mild-moderate COVID-19	Patients were hospitalized and within 14 days of symptom onset. They could not require more than 4 L/min of oxygen by NC or 40% venturi mask or supplemental ventilation Primary outcome was clinical status at day 15 (measured on 7 point ordinal scale)	Groups were well balanced, with regards to age, sex, co-existing conditions and concomitant therapies received. Median time from symptom onset was 7 days in all 3 groups	Analysis of the intent to treat population also did not find differences, as did sensitivity analyses. No difference was noted in secondary outcomes, including the proportion of those requiring mechanical ventilation or mortality. More adverse events were reported in the HCQ and HCQ+azithromycin groups (39% and 34%) than standard care only (23%) Prolongation of the QT interval was more common with HCQ
Geleris et al.[21] Observational study of HCQ in hospitalized patients with COVID	**Observational study of patients hospitalized with COVID at a large hospital in New York** Patients were classified as receiving HCQ if given at baseline (24 hrs after arrival at emergency department) or during follow-up (but before intubation or death) Propensity score methods used to reduce confounding and primary analysis used inverse probability treatment weighting (IPTW)	**Identified 811 HCQ and 565 NO-HCQ in the unmatched cohort and were able to identify 274 propensity matched patients** Baseline characteristics in matched cohort similar, including age, comorbidities and vital signs More HCQ patients received azithromycin, other antibiotics, tocilizumab Ferritin, LDH, CRP slightly higher in HCQ group	**Outcomes:** **Overall events:** HCQ: 262/811 (32.3%) No-HCQ: 84/565 (14.9%) HR 2.37 (95% CI 1.84 to 3.02) **MV analysis** HR 1.00 (95% CI 0.76 to 1.32) **Propensity score analyses** With IPTW: aHR 1.04 With matching: aHR 0.98 Adjusted for propensity score 0.97
Magagnoli J. et al.[24] Outcomes of hydroxychloroquine usage in United States Veterans hospitalized with COVID	**Multicenter, retrospective analysis of patients in VHA hospitals with COVID-19 who received HCQ, HCQ + azithromycin or standard care only** **Primary outcomes**: death or need for mechanical ventilation Association between treatment and outcome done using propensity score to adjust for clinical characteristics Medication exposure classified if documented as given during hospitalization (BCMA) but dose and duration not described. No evaluation of adverse events	**Identified 385 hospitalized Veterans who met criteria but excluded the 17 female Veterans - final analysis cohort was 368 adult male patients:** 97 HCQ, 113 HCQ+azithro, 158 Std care Were significant differences in baseline characteristics of baseline oxygen saturation, systolic BP, ALT/AST, albumin, bilirubin, WBC, lymphocytes, hematocrit, platelets, CRP, troponin I (baseline characteristics after propensity matching not available)	**Outcomes:** **Deaths:** HCQ 27.8%, HCQ+ azithro: 22.1%, Std care: 11.4% **Need for mechanical ventilation:** HCQ 13.3%, HCQ+azithro 6.9%, Std care 14.1% **Adjusted analysis of propensity matched groups** **Death** HCQ vs. no-HCQ: **aHR 2.61, (95% CI 1.1 to 6.17)** HCQ + azithro vs. no-HCQ: aHR 1.14 (95% CI 0.56 to 2.32) **Need for mechanical ventilation** HCQ vs. non-HCQ: aHR 1.43 (95% CI 0.53 to 3.79) HCQ+azithro vs. no-HCQ 0.43 (95% CI 0.16 to 1.12)

Mahevas et al.[23] Clinical efficacy of HCQ in patients with COVID-19 pneumonia who require oxygen: observational comparative study using routine care data	**Multi-center retrospective trial in 4 French hospitals -patients who received HCQ within 48 hours of admission vs. those who did not** Hospitalized adults without contraindications not treated with another therapy for COVID-19 and not admitted to ICU or with ARDS Dose 600mg daily Primary outcome composite of transfer to ICU within 7 days and/or death QT measured at baseline and 3-5 days later	**181 patients included – 84 received HCQ within 48 hrs of admission, 97 did not (8 did receive it later on) and made up the control group** Median age: 59 yrs HCQ vs. 62 yrs control Male sex: 78% HCQ vs. 65% control All comorbidities less frequent in HCQ group but other than HTN (45% HCQ and 58% control) were infrequent Median time from symptom onset to admission was 7 days.	**Outcomes:** **In IPTW analyses:** Primary outcome: 21% HCQ vs. 22% control (RR 0.93, 95% CI 0.48, 1.81) Results of sensitivity analyses similar to primary Evaluation of less severely ill subgroup (qSOFA < 2) also did not show benefit of HCQ on any outcome vs. control **Safety:** **8/84 (10%) patients experienced EKG changes requiring HCQ discontinuation** at median 4 days 7 had QTc increase > 60 msec and one patient had QTc > 500 msec 1 episode of left bundle branch block in a patient who received HCQ and lopinavir/ritonavir later
Rosenberg et al.[26]	**Retrospective study from random sample of patients at multiple hospitals in NYC, categorized into treatment groups based on exposure to HCQ, azithro, HCQ+azithro or neither** Primary outcome in-hospital mortality with additional secondary outcomes cardiac arrest and EKG findings (arrhythmia or prolonged QT) Cox proportional hazards model fit for time to death – controlling for treatment group and potential confounders	**Ultimately included 1438 patients** **735 HCQ + azithro** **271 HCQ** **211 azithro** **221 neither drug** HCQ initiated mean 1 day after admission (azithro median 0 days) Median age similar among groups (61.4-65.5 years) Combo group more likely to have low O2 saturation, abnormal chest imaging, elevated AST/ALT	**Outcomes:** **On unadjusted analyses, patients receiving HCQ, or HCQ + azithromycin had higher rates of ICU entry, need for mechanical ventilation or death** **Adjusted analyses: In-hospital death (each vs. no drug)** HCQ+ azithro: aHR 1.35 (95% CI 0.75 to 2.4) HCQ: aHR 1.08 (95% CI 0.63 to 1.85) Azithro: aHR 0.56 (95% CI 0.26 to 1.21) **Cardiac arrest:** **HCQ + azithro: aHR 2.13 (95% CI 1.12 to 4.05**) HCQ: aHR 1.91 (95% CI 0.96 to 3.81) Azithro: aHR 0.64 (95% CI 0.27 to 1.56) **HCQ vs. azithro aHR 2.97 (95% CI 1.56 to 5.64)** **Abnormal EKG:** HCQ + azithro: aHR 1.55 (95% CI 0.89 to 2.67) HCQ: aHR 1.50 (95% CI 0.88 to 2.58) Azithro: aHR 0.95 (95% CI 0.47 to 1.94) Adverse events more common in groups receiving HCQ, including diarrhea, abnormal EKG, arrhythmia
Tang et al.[20] Hydroxychloroquine in patients with COVID-19: an open-label, randomized, controlled trial	**Multi-center, open-label, centrally randomized controlled trial of HCQ + standard of care or standard of care alone in hospitalized patients with COVID-19 in China** Enrolled adults without contraindication to HCG hospitalized with mild/moderate or severe COVID-19 (stratified by severity). Dose was 200mg daily x 3 days, then 800mg daily for 14 days (mild/mod) or 3 weeks (severe)	**191 patients were screened and 150 were included (41 did not meet eligibility criteria) – 75 in each group** **Mean age:** 46 years, 55% female Mean time from onset of symptoms was 17 days 60% concomitant medication before randomization **99% had mild/moderate disease** Pts in HCQ group slightly older (48 vs. 44 yrs), more mild infection (20% vs. 9%) and more co-existing conditions (37% vs. 23%) but similar vital signs, symptoms and laboratory parameters.	**Outcomes:** At day 28, 85% of HCQ vs 81% of std care patients had negative viral PCR. Negative conversion at specific other time points was similar between groups No difference in time to negative conversion (8 vs. 7 days) Time to alleviation of symptoms similar (19 vs 21 days) HCQ did appear to result in more rapid normalization of CRP and lymphopenia

	Primary endpoint % negative viral PCR at day 28 Secondary outcomes were alleviation of symptoms, labs and radiology day 28	Some inflammatory markers slightly higher in the HCQ arm, including CRP (9.9 vs. 7.4) and IL-6 (12.9 vs. 8.9) but consistent with mild/mod disease	**Safety: No mention made of EKG monitoring or cardiac adverse events, but overall adverse events were more common with HCQ (30%) than without (9%), including diarrhea in 10%.**
Chen et al.[22] Open label randomized trial of HCQ vs standard care in hospitalized patients with mild COVID pneumonia	**Open-label RCT of adults mild COVID-19** (PaO2/FiO2 > 300 mmHg SaO2 > 93%) randomized to HCQ 200mg BID x 5 days + std. care OR Standard care alone (*oxygen, antiviral agents, antibacterials and immunoglobulin with or without corticosteroids)* **Primary endpoint:** Differences in time to clinical recovery 5 days after enrollment. TTCR was only assessed in those patients having the symptom at baseline **Secondary:** progression to severe illness, radiographic improvement day 0 to 6 chest CT	**Demographics:** 62 patients were enrolled and all completed study Mean age 45 years (44 yr HCQ vs 45 yr std) 47% male (48% vs. 45%) At baseline fever: 71% HCQ vs. 55% of std care At baseline cough: 71% HCQ vs. 48% of std care ***No other demographics or baseline characteristics provided to identify relative similarity in severity of illness, comorbidities or risk for poor outcomes***	**Results:** **TTCR Fever:** 2.2 d HCQ vs. 3.2 d std.(p=0.0008) **TTCR cough:** 2.0 d HCQ vs. 3.1 d std. (p=0.0016) Progression to severe illness in 4 of 62 patients in std. treatment arm (6.5%) vs. none in HCQ arm (not defined) **Overall chest CT improved:** 81% HCQ vs. 55% std. care **Safety:** Two patients on HCQ developed mild adverse reactions – one rash and one headache
Protease inhibitors: Lopinavir/ritonavir (Lop/rit), Darunavir + ritonavir or cobicistat (DRV/r, DRV/c)– antiviral agent used in treatment of HIV infection with in vitro activity against several coronaviruses leading to study and use in COVID-19. Lop/rit appears more active in vitro because inhibits COVID-19 protease, but possible that would require higher doses than currently used to be clinically effective and clinical trials are ongoing. Darunavir (with ritonavir or cobicistat) does NOT appear to have activity in vitro or in vivo efficacy			
Cao et al.[33] Randomized trial of lop/rit vs. standard care for severe COVID in China	**Randomized, open-label trial in patients in patients with severe COVID-19 (**O2 sat. ≤ 94% or PaO2/FiO2 ≤ 300 mmHg) Lop/rit. (400mg/100mg) BID (n=99 in ITT but 94 received treatment as assigned) vs. Standard therapy (n=100) For 14 days Primary outcome: time to clinical improvement based on 7 point ordinal scale (1 = resumption of normal activity, 7 = death)	**Demographics:** Median age 58 years with few comorbidities Median 13d from illness onset At baseline – majority were ordinal score 4 (in hospital requiring supplemental oxygen) More patients in std. care arm were on vasopressors, renal replacement, non-invasive or invasive ventilation 95% in each arm received antibiotics 32% lop/rit and 35% std. care received glucocorticoids for median of 7 and 6 days, resp.	**Primary outcome (Time to clinical improvement) 16 days for each group** **28 day mortality (ITT)** Lop/rit: 19% vs. Std care: 25%. Diff -6% (95% CI -17, 6) Length of ICU stay: 6 days Lop/rit vs. 11 days std care. Difference -5 days (95% CI -9, 0) undetectable viral RNA did not differ between groups at any time point ***At day 28, only 60% of lop/rit and 59% of std. care were undetectable*** Adverse events 48% of lop/rit and 50% of std. care and grade 3 or 4 AE in 21% lop/rit vs. 11% Std. care Nausea, vomiting, diarrhea more common with lop/rit - ***Serious AE of respiratory failure/ARDS in 13% lop/rit vs. 27% std. care***
Zhu et al.[72] Small retrospective comparison of Lop/rit vs. arbidol in China	**Retrospective analysis of Lop/rit** 400/100 q12h for 1 week vs. arbidol 0.2g three times daily in hospitalized patients in China All patients received oxygen and inhaled interferon (IFN-α2b) 5 million units q12h Primary outcomes: antiviral effect and safety of lop/rit and arbidol	**Demographics: lop/rit n=34, arbidol n=16** Median age: Lop rit 41 yrs, arbidol 27 yrs Male sex: Lop/rit 59%, arbidol 38% CRP on admission: Lop/rit 7.7, arbidol 1.1	**Results:** **Day 7 viral load:** undetectable 24% lop/rit vs 50% arbidol **Day 14:** undetectable in 56% lop/rit and 100% arbidol Patients in arbidol arm had shorter duration of positive RNA (p<0.01) 3 patients in each group developed elevated ALT in the first week (<125 U/L) – no other side effects mentioned

IL-6 inhibitors: Tocilizumab(Toci) / Sarilumab(Sari) / Siltuximab (Siltux) **– anti-IL-6 biologics used for Rheumatoid arthritis**

Extremely limited data based on evidence that severe COVID-19 disease is often associated with elevated IL-6, and a syndrome consistent with cytokine release syndrome (CRS). From China, has been shown that elevated IL-6 levels are associated with poor outcomes with COVID-19[73,74]

Added to Chinese guidelines for patients with severe COVID-19 and associated CRS, and in indicated for CRS associated with CAR-T therapy[75]

Associated with significant side effects in RA, including **serious infections**, **gastrointestinal perforation** *and anaphylaxis. In RA patients need to be screened and initiated on therapy for latent or active tuberculosis prior to initiation of therapy*

Press Release: high level results of COVACTA trial of tocilizumab vs. placebo	**Randomized, placebo controlled trial of tocilizumab in severe COVID-19** Patients were adults hospitalized with COVID-19 and O2Sat ≤ 93% or PaO2/FiO2 < 300 mmHg Patients with known allergy, suspected active infections (TB, viral, bacterial or fungal), pregnant, or with ALT/AST > 10 x upper limit of normal or platelets < 50K /mL or ANC < 1000 /mL were excluded Dose was: 8 mg/kg (up to 800mg) vs. placebo with 1 additional dose allowed if no improvement Primary outcome clinical status using 7-category ordinal scale at day 28	450 persons were enrolled but no further demographic information is available, although additional analyses are ongoing as stated in the press release	**Outcomes:** **Primary outcome:** Clinical outcome was not significantly different at day 28 using the 7 point ordinal scale with OR 1.19, (95% CI 0.81 to 1.76), p=0.36 No difference was seen in mortality at day 28 Tocilizumab 19.7%, placebo 19.4% Difference 0.3% (95% CI -7.6% to 8.2%), p=0.94 Time to hospital discharge or 'ready to discharge' was shorter with tocilizumab (median 20 days vs. 28 days for placebo), however the difference cannot be considered statistically significant as the primary endpoint was not met. No statistical difference in ventilator-free days was demonstrated between tocilizumab and placebo (median 22 days vs. 16.5 days) It was reassuring that infections at 4 weeks were not greater with tocilizumab than placebo (38% vs. 41%) or with serious infections (21% vs. 26%) and no new safety signals were identified Full published results are awaited to examine patient characteristics

Press Release: CORIMUNO-19 PARIS[76] **Multi-center, open-label, RCT of Tocilizumab in hospitalized patients with moderate or severe COVID-19 in Paris**	One of a series of ongoing RCT in France (CORIMUNO trials) of toci + standard of care (SOC) vs. SOC alone 2 cohorts of patients – one with moderate and another with severe COVID-19 infection Dose is 8 mg/kg IV with option for 2nd dose at day 3 Primary outcome: need for ventilation (invasive or non-invasive) or death at day 14	Randomized 65 patients to tocilizumab + SOC and 64 patients to SOC alone No other information available at this time regarding demographics, baseline characteristics, similarity between groups	**In the press release, investigators stated "a significantly lower proportion of patients reached the primary endpoint in the tocilizumab arm". Results of the study will be submitted for publication in a peer-reviewed journal** Authors stated the results should be confirmed independently by additional trials, but given the pandemic context they felt ethically obligated to disclose the information, pending peer review and while continuing to accrue longer follow-up
Press release: REGENERON – Regeneron and Sanofi provide update on U.S. Phase 2/3 adaptive designed trial of Kevzara (**sarilumab)** in hospitalized COVID-19 patients	Press release on 4/27/20 of results after analysis by independent data monitoring committee of all phase 2 and 3 data resulting in an amendment eliminating the "serious" illness arm and only continuing "critical" Phase 2 portion 457 patients and compared 200mg IV, 400mg IV and placebo (single dose) with either severe illness (28%) or critical illness (49%) or multi-system organ dysfunction (23%) Note – sarilumab was given intravenously in this trial not, subcutaneously as currently FDA approved for rheumatoid arthritis	Phase 2 trial demonstrated sarilumab rapidly lowered CRP, meeting primary endpoint, with no new safety signals Analysis of clinical outcomes in the Phase 2 trial was exploratory and pre-specified to focus on the "severe" and "critical" groups and sarilumab had no notable benefit on clinical outcomes when combining the "severe" and "critical" groups, versus placebo. negative trends for most outcomes in the "severe" group, and positive trends in the "critical" group. Subsequent to the IDMC review, Regeneron and Sanofi reviewed the discontinued "severe" group	**Analysis combining severe and critical cases on clinical outcomes identified no notable benefit, but negative trends in "severe" group and positive trends in "critical" group for all outcomes** Note that in phase 3 data: negative trends seen in the Phase 2 trial (n=126) were not reproduced in Phase 3 trial (n=276), and clinical outcomes were balanced between sarilumab and placebo, with outcomes that were better than expected based on prior reports **In a follow up press release on 7/2/20, Regeneron and Sanofi announced they were discontinuing the phase 3 trial after the remaining arm failed to meet its primary or secondary endpoints.**
Gritti et al. Case series of 21 patients with COVID-19 in Italy treated with **siltuximab**	Retrospective analysis of 21 patients who received siltuximab 11 mg/kg IV over 1 hour – 2nd dose could be given, as part of compassionate use program. All patients were followed up for at least 7 days Patients had confirmed COVID-19 by clinical and radiological assessment and ARDS	**Demographics:** Median age: 64 yrs. (range 48-75) 86% male 90% had fever, 62% dry cough, 71% dyspnea **Comorbidities:** HTN (43%), DM (24%), cardiovascular disease (19%) Baseline CRP elevated in all patients (median 23.4 mg/dL), IL-6 available for 19 patients and was elevated. Median PaO2/FiO2 127 All 21 patients were on CPAP or non-invasive mechanical ventilation 5/21 patients received 2nd dose	**Outcomes:** CRP normalized by day 5 and stable for all 16 patients with available data through follow-up **Improvement 33%, stabilized 43%, worsened 24%** 5/21 required intubation 7/21 no longer required CPAP/ventilation 1 patient had cerebrovascular accident No other outcomes reported and no mentioned of adverse events Cohort study of matching patients vs. standard care ongoing.
Somers et al.	**Retrospective analysis of patients hospitalized in several Detroit hospitals with COVID-19 requiring mechanical ventilation who received**	**Demographics:** In matched cohort 78 pts received TOCI, 76 standard care.	**Results:** **Mortality at 14, 21 and 28 days was significantly lower in the tocilzumab arm**

Retrospective cohort from Detroit of tocilizumab vs. controls	**tocilizumab as part of a hospital protocol vs. those who did not** Other therapies were at discretion of the treating physician. Calculated propensity score by MV logistic regression, then applied IPTW to attempt to balance group and adjust for confounding **Primary endpoint:** Survival probability	Control patients were older (60 vs. 55 yrs.), more likely to have chronic pulmonary disease (28% vs 10%) or chronic kidney disease (49% vs. 35%). Control patients also had a higher PaO2/FiO2, lower albumin, higher d-dimer. They also had numerically lower use of corticosteroids and therapeutic anticoagulation and were significantly less likely to undergo prone positioning	9% vs. 26% at day 14 14% vs. 33% at day 21 18% vs. 36% at day 28 Length of stay and duration of mechanical ventilation were not significantly different Superinfections were significantly more common in patients receiving TOCI (54% vs. 26%), including pneumonia (45% vs. 20%) *While there was significant attention paid to matching with statistical modeling, groups do differ in ways known to be associated with mortality (age, steroid use, prone positioning) which may have influenced the results. The significant increase in infections is concerning although this did not appear to alter mortality*
Guaraldi et al. **TESEO multicenter, retrospective observational cohort in Italy of patients with severe COVID-19 pneumonia**	Observational cohort of patients admitted to 3 centers in Italy from Feb-April 2020 with severe COVID-19 Excluded patients with severe leukopenia, thrombocytopenia, active infections or risk for gastrointestinal perforation or any chronic or current corticosteroids All patients received HCQ, azithro, lop/rit, oxygen and LMWH for VTE prophylaxis Eligible patients (SaO2 < 94%, PaO2/FiO2< 300 mmHg or worsening) received tocilizumab 8 mg/kg (max 800mg) or SQ tocilizumab 324 mg once (162 mg each thigh) if IV was not available. Second dose could be given 12 hrs later Primary outcome composite of death or need for invasive mechanical ventilation	**Demographics:** Study population = SQ TOCI (n=91), IV TOCI (n=88), standard care (n=365) Overall median age 67 years, but younger in IV TOCI group (63 yrs) vs. standard care (69 years) PaO2/FiO2 lower with TOCI (169 vs. 277 mmHg) SOFA higher with TOCI (3 vs. 2) Duration symptoms longer with TOCI (7 vs. 5 days) Corticosteroids started in 30% of TOCI and 17% of standard care groups	**Outcomes:** No difference in need for mechanical ventilation TOCI vs. standard care (18% vs. 16%) Death lower with TOCI (7% vs. 20%), p=0.0007 Composite endpoint of need for mechanical ventilation or death by day 14 was lower with TOCI (22.6%) vs. standard care alone (36.5%) aHR was 0.61 (95% CI 0.4 to 0.92) Similar outcomes seen with IV and SQ TOCI Stratified analysis suggested benefit was better in patients with PaO2/FiO2 < 150 mmHg; aHR 0.19 (95% CI 0.08 to 0.44) Adverse events included 1 infusion reaction, 1 case severe neutropenia. New infections occurred in 13% TOCI vs. 4% of standard care patients, including one fatal HSV reactivation with liver failure
Rossotti et al. **Retrospective matched cohort in Italy of tocilizumab vs. standard care**	**Retrospective observational cohort of patients with severe or critical COVID-19 infection that compared patients who received TOCI by local protocol vs. a matched cohort of patients who did not**	**Demographics:** **74 patients who received TOCI were matched 1:2 to 148 patients who received standard care only** Median age: 59 years in each group Critical disease in 80% TOCI and 70% std care groups	**Results:** **Overall mortality was lower in patients who received TOCI with HR 0.5 (95% CI 0.25 to 0.95)** Of interest, this benefit was only seen in critical patients, not those with severe disease.

	Hazard ratios were calculated to compare survival between groups	PaO2/FiO2 in patients with severe disease (but not in critical disease) was lower in TOCI group Most patients in both groups receive LOP/rit and HCQ and around 10% received remdesivir No other information was available on comorbidities, or other risk factors	Baseline IL-6 values or number of doses was not associated with survival TOCI was associated with a longer hospital LOS with Hr 1.66 (95% CI 1.09 to 2.52) Receipt of TOCI outside the ICU was associated with the sudden need of intubation after administration (log rank 12.659, p<0.001) 27 infectious complications occurred in 24 patients (32%). 11 were considered severe (sepsis, candidemia, lung abscess and epidural abscess) and one patient died from septic shock
Other immunomodulatory agents: (IL-1 inhibitors, JAK inhibitors, BTK inhibitors): affect immune system at various points with goal to reduce hyperinflammatory state			
Cavalli et al. **Case series with historical control of patients treated with high-dose intravenous anakinra or low dose subcutaneous anakinra (IL-1 inhibitor) vs. standard care alone**	Retrospective review of patients who received anakinra for COVID-19 in large hospital in Italy. Criteria for anakinra were COVID-19 with moderate to severe ARDS with hyperinflammation on noninvasive ventilation: Dosing was 5 mg/kg IV over 1 hour twice daily until specific criteria were met (75% reduction in CRP, improved respiratory parameters) followed by SQ anakinra 100mg BID x 3 days Some patients received 100mg SQ BID only Controls were historical patients who received standard care and would have met criteria for anakinra and also did not receive other immunomodulatory therapy	**Demographics:** 16 control patients were compared with 29 patients who received high-dose IV anakinra, but also included 7 patients who received low dose SQ anakinra Mean age: 70 years in control group, 62 years with high dose anakinra, majority male. Control patients had higher ferritin, CRP Anakinra arm had lower PaO2/FiO2 and more met criteria for severe ARDS	**Results:** Anakinra patients had more rapid reduction of CRP Showed overall higher survival at 21 days with anakinra but similar proportion of patients discharged and no difference in mechanical ventilation-free survival Treatment discontinued in 7 patients due to adverse events (24%) after median duration 9 days – 4 cases of bacteremia and 3 increases in liver enzymes Data is hypothesis generating but groups were very small, not well matched and use of historical control may generate bias
Corticosteroids			
Horby et al. **Randomized, adaptive platform trial of dexamethasone vs. standard care in hospitalized patients with COVID-19**	Investigator-initiated, randomized, controlled open-label trial of multiple possible treatment arms vs. standard care This publication examines the outcomes of those randomized to dexamethasone vs. standard care Criteria included hospitalized patients with COVID-19. If they had a contraindication to	**Demographics:** Of 11,320 patients randomized – 9355 were eligible to be randomized to dexamethasone and ultimately 2104 were randomized to dex and 4321 to usual care, with the remainder randomized to another study arm Of these 24% of each group did not require supplemental oxygen, while oxygen was given in 61% of dex and 60% of usual care patients. 15% of dex and	**Results:** 28 day mortality occurred in 21.6% of dex and 24.6% of usual care patients: RR 0.83 (95% CI 0.74 to 0.92) The difference was greatest in those on mechanical ventilation (29% vs. 40.7%), RR 0.65 (95% CI 0.51 to 0.82) It was also significant on those requiring supplemental oxygen (21.5% vs. 25%), RR 0.80 (95% CI 0.73 to 0.96)

	dexamethasone or it was not available at their hospital, that randomization arm was not available. The standard of care arm included patients who would have been eligible for dexamethasone but were randomized to standard care Dosing: dexamethasone 6 mg IV or PO daily for up to 10 days Primary outcome was mortality within 28 days. Secondary outcomes included time to discharge or proportion requiring invasive mechanical ventilation or death (in those not on mechanical ventilation at baseline)	16% of usual care patients were on invasive mechanical ventilation at baseline The majority were male (64% each group) Mean age was 67 yrs (dex) and 66 years (usual care) 56% of patients in each group had at least one comorbidity (most commonly diabetes or heart disease) Mean days from symptom onset was 6 days in those not requiring oxygen, 9 days in those receiving oxygen and 13 days in those on mechanical ventilation Tocilizumab or sarilumab were only given in 1% (dex) and 2% (usual care) of patients, and hydroxychloroquine, or lopinavir/ritonavir were 1% or less. Azithromycin was given to 23% (dex) and 24% (usual care) of patients	For those NOT requiring oxygen, a benefit was not demonstrated (17% vs. 13.2%), RR 1.22 (95% CI 0.93 to 1.61), p=0.14 (when adjusted for age) Overall results of secondary outcomes: Discharge from hospital within 28 days occurred in 64.6% of dex and 61.1% of usual care patients, RR 1.11 (95% CI 1.04 to 1.19) For those not on mechanical ventilation at baseline, 23.9% and 25.8% of dex and usual care patients respectively, either received mechanical ventilation or died Overall this study design was solid, although it is impossible to assess the impact of dexamethasone in combination with other therapies such as remdesivir or tocilizumab, given few patients received these. The mortality rate was also rather high in patients not receiving oxygen, and practice differs in the UK from the US where elderly patients are less likely to be offered mechanical ventilation. Still this study supports a benefit in a well-described and well matched group of elderly, hospitalized patients with COVID-19, especially the sickest patients

+The effective concentration is the concentration of product at which virus replication is inhibited by 50 percent (e.g., EC_{50} for cell-based assays). Cytotoxicity tests use a series of increasing concentrations of the antiviral product to determine what concentration results in the death of 50 percent of the host cells (median cellular cytotoxicity concentration or CC_{50})

Table 2: Selected Characteristics of Potential Therapeutic Agents for COVID-19

DRUG	In vitro activity AND MECHANISM+	PHARMACOKINETICS / PHARMACODYNAMICS*	DOSING AND ADMINISTRATION**
Lopinavir/ritonavir	In vitro data vs. many coronaviruses, including SARS and MERS – early data suggested activity vs. COVID-19	PK well described for HIV – ritonavir acts as pharmacokinetic booster to increase levels of lopinavir Bioavailability requires administration with ritonavir Metabolized by CYP3A4	Should be given with food which could be an issue in hospitalized patients 400/100mg twice daily for 7-14 days has been studied
Chloroquine (CQ)	EC_{50} 1.13 uM CC_{50} > 100 uM Thought to exert activity against coronaviruses by concentrating in acidic intracellular organelles such as lysosomes and increasing pH within vesicles and inhibit viral replication. Have also been suggested to play a role preventing viral entry via endosomes May also function as immunomodulators	Bioavailability 90% Protein binding 55% V_d 200-300 L/kg – extensive tissue distribution to liver, spleen, kidney and lung C_{max} 0.06-0.1 mcg/mL : 300mg single dose **Half-life 10-60 days** Metabolized in liver (2C8, 3A4) – primary metabolite desethylchloroquine 50% excreted unchanged in urine	*Note 250mg CQ phosphate = 150mg CQ base (comes as 250mg, 500mg chloroquine phosphate tablets)* Optimal treatment dose unknown: Dose recommendations from FDA Emergency Use Authorization (**for adults weighing 50kg or more): 1gram CQ phosphate (600mg CQ base) on day one followed by 500mg CQ phosphate (300mg CQ base) daily for total 4-7d** **Chinese consensus guidelines recommend 500mg chloroquine phosphate (300mg CQ base) BID x 10 days** *Daily dose should not exceed 2.3 mg/kg actual body weight* Recently – DMSB stopped high-dose arm (500mg BID) of ongoing RCT in Brazil due to high rate of QT prolongation and 2 cases of torsades de pointes[19]
Hydroxychloroquine	Compared with CQ – HCQ EC_{50} was 0.72 uM vs. 5.47 for CQ Similar proposed mechanisms of activity to CQ vs. COVID-19, although in vitro data suggests increased potency When given prior to viral challenge: EC_{50} 6.25 uM at 24 hr and 5.85 uM at 48 hr	Mean steady state concentration in patients on 400mg daily = 0.42 mcg/mL Bioavailability variable in rheumatoid arthritis 30-100% Large volume of distribution **Half-life 40 days** 15-30% excreted unchanged in urine In study by Gautret- mean HCQ concentrations (on 200mg TID) were reported to be 0.46 +/- 0.2 ug/mL PK study in 13 critically ill patients on 200mg TID for 7 days found only 8/13 achieved a level at least 1 mg/L (at mean of 2.7 days), and 2/13 had concentrations > 2 mg/L. After modeling they	*Note: supplied as 200mg tablets – crushing or breaking of tablets not recommended* Optimal treatment dose unknown: Based on modeling and in vitro activity – **400mg BID x 1 day, followed by 200 mg BID for 4 days** Other suggested doses: 400mg daily to BID x 5-10 days 200mg TID x 10 days[30] Compounding suspensions for oral/enteral administration[79]

		suggested a loading dose of 800mg x 1 followed by 200mg BID would most likely achieve a level of 1-2 mg/L[77] Another study in 14 critically ill patients (5 on renal replacement therapy and one on ECMO) noted toxic concentrations in several patients by day 5 of therapy and therapy was stopped or altered in 2 patients, one for prolonged QTc and another for severe hypoglycemia[78]	
Remdesivir	Nucleoside analog, broad-spectrum antiviral – inhibits viral replication In vitro EC_{50} of 0.77 uM	High first pass effect reduces oral bioavailability Linear PK at doses 3-225mg IV, including with repeated doses of 150mg IV once daily - rapidly distributed to peripheral blood mononuclear cells (PBMCs) w/in 2 hours then activated to nucleoside triphosphate Metabolized to active metabolite **GS-443902** with prolonged intracellular half-life (>35 hrs) and AUC within mononuclear cells	PK data suggests 30minute infusions may maximize intracellular concentration (vs. 2 hr) Dose in COVID19 Clinical trials and Expanded access = 200mg IV once then 100mg IV daily for 5 or 10 days total
Tocilizumab	IL-6 inhibitor being studied to treated suspected cytokine release syndrome (CRS) with COVID-19 in lungs Holds FDA indication for CRS related to CAR T-cell therapy	Given by intravenous infusion – typically in 100 mL 0.9% or 0.45% sodium chloride over 1 hour Nonlinear elimination (Michaelis-Menten kinetics) – half-life is concentration dependent (ranges 11-19 days) **SQ formulation should NOT be given intravenously – NO data on use of SQ tocilizumab for treatment of COVID-19**	Dose given was 400mg IV x 1 over 60 minutes with a minority of patients given a second dose 12 hours after the first
Sarilumab	IL-6 inhibitor FDA indicated for the treatment of rheumatoid arthritis being studied in phase 2/3 trials to reduce cytokine release syndrome (CRS) with COVID-19	Administered SQ – PK based on 150mg and 200mg mult. Dose Tmax reached at 2-4 days Eliminated through linear and non-linear pathways with conc. Dependent $t_{1/2}$ (8-10 days) but detectable for 28-43 days	For RA given as a SQ injection every 2 weeks – supplied as prefilled, single dose pens or syringes of 150mg or 200mg Current phase 2/3 study is looking at a single dose of "low dose", "high dose" or standard care **BUT IS BEING GIVEN INTRAVENOUSLY AS A SINGLE DOSE (dose unclear)**
Siltuximab	IL-6 inhibitor FDA indicated for treatment of multicentric Castleman's disease Observational case-control study in Italy being done based on compassionate use	Administered IV with Cmax by end of infusion although steady state not reached until the 6th infusion Mild-moderate renal or hepatic impairment did not significantly affect PK	Administered as an IV infusion over 1 hour (diluted in 250mL D5W)– data for CRS in COVID unknown, but for FDA indication, dose is 11 mg/kg Supplied as 100mg and 400mg single dose vials

**PK/PK, dosing, general information from Kucers' the Use of Antibiotics, 7th Ed, 2019*

***Dosing is taken from tertiary references, published literature and pharmacokinetics and in vitro data but should be discussed with local experts and is not intended to imply a recommendation*

+The effective concentration is the concentration of product at which virus replication is inhibited by 50 percent (e.g., EC_{50} for cell-based assays). Cytotoxicity tests use a series of increasing concentrations of the antiviral product to determine what concentration results in the death of 50 percent of the host cells (referred to as the median cellular cytotoxicity concentration or CC_{50})

Table 3: Safety and Drug Interactions of Potential Therapeutic Agents for COVID-19

Drug	Common or Serious Adverse Events	Drug Interactions	Comments
Lopinavir/ritonavir	**GI Symptoms (diarrhea) which appeared to be significant in COVID-19 patients** -pancreatitis -liver enzyme abnormalities	Substrate and inhibitor of CYP3A4 Inhibits CYP2D6 but less Major interactions -anticoagulants -antiarrhythmics -statins -calcium channel blockers -immunosuppressants -PDE5 inhibitors	All drug interactions should be closely reviewed by a pharmacist prior to initiation and meds adjusted as indicated – Excellent resource is University of Liverpool interaction tracker Diarrhea and other gastrointestinal side effects common
Chloroquine[80]	-**QT prolongation, arrhythmia** and conduction abnormalities -**Gastrointestinal distress**, nausea, diarrhea, abd. Pain -**Neurotoxicity and psychiatric effects** (agitation, depression, anxiety, psychosis, **seizures**, **extrapyramidal reactions**) -**Hypoglycemia (with or without antidiabetic drugs**) -**Hemolytic anemia with G6PD deficiency, leukopenia** **-Skin reactions: rash/pruritis, Erythema multiforme – may cause exacerbations of psoriasis or porphyria** - Symptoms of overdose include hypotension, AV block, arrhythmias, and electrolyte disturbances **A single 500mg tablet can be fatal to a child** **Study in Brazil comparing high dose (600mg twice daily x 10 days) vs. low dose (450mg twice daily x 1day, then daily for 4 days) as treatment of COVID-19 in hospitalized patients was stopped early, after 81 patients were enrolled.** Overall fatality was 27% and mortality by day 13 was higher in the high dose arm than in the low dose arm (39% vs. 15%). QTc > 500 msec occurred more frequently in the high-dose arm (19%) than in low dose arm (11%) and difference was even more marked in patients with confirmed COVID-19 (24% vs. 4%)	Substrate of CYP2C8, 3A4 Inhibits CYP2D6 Inhibits CYP2D6 and to lesser degree CYP3A4 Increased levels of drugs metabolized by CYP2D6 -beta-blockers -antipsychotics -antidepressants Increased levels of digoxin Increased risk of QT prolongation with other medications that prolong QT	**QT should be monitored prior to initiation and drug avoided if QT > 490 msec**. Ideally patients should be on telemetry, and if tele QTc concordant to EKG QTc can use telemetry for further QTc monitoring: ○ For patients not on telemetry a repeat EKG should be taken after starting CQ and considered daily if risk factors ○ Discontinue all other QT prolonging agents, if possible ○ **If QTc increases by > 50 msec, or absolute QTc > 500 msec, discontinuation should be strongly considered** ○ Of note, other modifiable risk factors (K+, Mg++) should be monitored and controlled for ○ **Azithromycin may also prolong the QTc and has been shown to increase the risk of sudden cardiac death** Review for drug interactions prior to administration Extreme caution or avoid in patients with history of seizures, conduction abnormalities, preexisting anemia, severe liver dysfunction **G6PD testing prior to initiation**

Hydroxychloroquine[81]	**Generally considered better tolerated than CQ** - **Pruritis,** hypersensitivity, may exacerbate psoriasis or porphyria – a case of a severe exacerbation of psoriasis when given for COVID-19 has been reported[82] -**Can prolong QTc**, PR and QRS, which has resulted in fatal arrhythmia: Risk factors include female gender, age ≥ 65 yrs., baseline prolonged QT/QTc, congenital long QT syndrome, family history of sudden cardiac death before age 50, cardiac disease, electrolyte disturbances, bradycardia, acute neurologic events, DM and autonomic neuropathy as well as use with concomitant drugs that can prolong QT – risk is **DOSE DEPENDENT** -**Gastrointestinal distress**, nausea, diarrhea, abd. Pain -**Neurotoxicity and psychiatric effects** (including suicidal ideation, seizures, extrapyramidal reactions) muscle weakness -**Hypoglycemia** (with or without antidiabetic drugs) -Hemolytic anemia with G6PD deficiency (less of concern than with CQ), leukopenia - **Symptoms of overdose include hypotension, AV block, arrhythmias, seizures and hypokalemia which often occur within 1-3 hours of ingestion**[83]	Substrate of CYP2C8, 3A4 Inhibits CYP2D6 Inhibits CYP2D6 and to lesser degree CYP3A4 (increased level of cyclosporine has been reported) Increased levels of drugs metabolized by CYP2D6 -beta-blockers -antipsychotics -antidepressants - Increased levels of digoxin Antacids may reduce absorption when given simultaneously with HCQ – separate by 4 hours Increased risk of QT prolongation with other medications that prolong QT, including but not limited to (Class 1A, 1C, III antiarrhythmics, certain antidepressants, antipsychotics, fluoroquinolones, macrolides, 5-HT3 receptor antagonists)	Contraindicated in patients with pre-existing retinopathy of the eye **EKG should be done at BASELINE** - QT should be monitored prior to initiation and drug avoided if QT > 490 msec. Ideally patients should be on telemetry, and if tele QTc concordant to EKG QTc can use telemetry for further QTc monitoring: ○ For patients not on telemetry a repeat EKG should be taken after starting CQ and considered daily if risk factors ○ Discontinue all other QT prolonging agents, if possible ○ If QTc increases by > 50 msec, or absolute QTc > 500 msec, discontinuation should be strongly considered ○ Of note, other modifiable risk factors (K+, Mg++) should be monitored and controlled for ○ **Azithromycin may also prolong the QTc and has been shown to increase the risk of sudden cardiac death** Review for drug interactions prior to administration Glucose should be monitored closely in patients, especially those with DM on insulin or other medications along with HCQ, lower doses may be required Extreme caution or avoid in patients with history of seizures, conduction abnormalities, preexisting anemia, liver dysfunction, renal dysfunction
Remdesivir	Limited safety data in humans Preclinical data showed high safety margins of both remdesivir and GS-441524 with > 3.5 fold margins in most toxicity assays. Animal data suggest a low risk for CNS, respiratory or cardiovascular toxicity at human doses	No published data available	In placebo controlled trial in China adverse events occurred in 66% of remdesivir and 64% of placebo patients Rash – 7% with remdesivir vs. 3% placebo Thrombocytopenia - 10% remdesivir vs. 6% placebo AST elevation – 5% remdesivir vs. 12% placebo Serious adverse events occurred in 18% remdesivir and 26% placebo patients (6% vs. 13% were grade 3)
Tocilizumab	Increases risk of severe and opportunistic infections when used for rheumatoid arthritis, including active tuberculosis, invasive fungal infections, bacterial, viral and other opportunistic pathogens Neutropenia (1.8-3.4%) Hypersensitivity, including anaphylaxis (0.1-0.2%) Hepatotoxicity Rare cases of gastrointestinal perforation	Live vaccines should be avoided with tocilizumab as clinical safety has not been established May result in increased activity of several CYP enzymes (CYP1A2, 2B6, 2C9/19, 2D6, 3A4) due to inhibition IL-6	AST/ALT should be ordered prior to therapy and in RA tocilizumab is recommended to be discontinued if > 5 x upper limit of normal WBC should be done prior to administration and recommendation in RA is to discontinue if the ANC <500 Platelet count is recommended prior to initiation and in RA recommendation to discontinue if platelets < 50

	Increased total cholesterol, triglycerides, LDL and/or HDL	Patients on drugs metabolized through CYP enzymes with narrow therapeutic indices should be monitored	
Sarilumab	**Black box warning for increased risk of serious risk of serious infections leading to hospitalization and death, including bacterial (especially pneumonia), viral (zoster reactivation), fungal and other opportunistic infections. Cases of tuberculosis have also been reported** Neutropenia (7-10%), thrombocytopenia Elevation of transaminases Increases in LDL, HDL, triglycerides **Rare cases of GI perforation – especially with diverticulitis or in patients on concomitant NSAIDs or corticosteroids** Hypersensitivity reactions (0.3%)	Live vaccines should be avoided during treatment due to increased risk of infection related to immunosuppression caused by sarilumab IL-6 inhibitors may impact CYP450 enzymes – in patients on simvastatin, one week after 200mg SQ sarilumab, simvastatin conc. Decreased by 45% This may result in significant interaction with other drugs metabolized primarily through CYP450 with a narrow therapeutic index	Sarilumab should be AVOIDED in patients with documented or strongly suspected bacteria, fungal, opportunistic or viral infections (other than COVID-19) CBC should be checked prior to administered with sarilumab avoided if ANC < 500 cells/mm^3 or PLT < 50,000 cells/mm^3 Transaminases should be monitored and sarilumab generally avoided if AST/ALT > 5 X ULN No data exists on safety in patients with hepatic impairment including patients with positive HBV or HCV serology
Siltuximab	**Warnings for active severe infections, infusion reactions and GI perforation** Contraindicated if severe hypersensitivity **Should NOT be administered to patients with severe infections until resolved** Infusion reactions in 5-6% of patients, and 1 case of anaphylaxis in 945 patients Rash/pruritis in 28% vs. 12% with placebo	Live vaccines should be avoided during treatment due to increased risk of infection related to immunosuppression May result in increased activity of CYP enzymes due to inhibition IL-6. Patients on drugs metabolized through CYP enzymes with narrow therapeutic indices should be monitored	Infusion should be stopped if signs of anaphylaxis For mild to moderate infusion reactions, if the reaction resolves, it can be restarted at a lower infusion rate (consider premedication with antihistamines, acetaminophen)

Appendix 1: Investigational Therapeutic Agents under evaluation as Possible Treatments of Coronaviruses

Medication	Study Design	Results	Comments
Favipiravir (T-705) broad spectrum antiviral (RNA-dependent RNA polymerase inhibitor) with activity vs. SARS, West Nile, Zika, Yellow Fever, Chikungunya, Poliovirus and other that has been studied in severe influenza and Ebola and suggested as a treatment for pandemic influenza In addition to influenza			
Galidesivir Antiviral with activity against COVID-19 and yellow fever virus – randomized, placebo controlled pharmacokinetic study – given as an IV infusion			
Camostat mesllate serine protease inhibitor that may block entry of COVID-19 into cells with positive data in mice **NCT04321096**, **NCT04338906** (WITH HCQ) NCT04353284			
Nafamostat (RACONA study) RCT of continuous infusion of nafamostat vs. placebo			
Mavrilimumab –Single dose IV in severe COVID (but not mechanically ventilated)			
Gimsilumab –human monoclonal antibody that acts on GM-CSF (Roivant) in development for autoimmune diseases and malignancy			
Leronlimab (PRO-140) CCR5 antagonist previously studied for HIV and cancer **NCT04343651** phase 2 trial 700mg leronlimab vs. placebo			
Arbidol –non-nucleoside broad-spectrum antiviral with immune-enhancing effect			
Danoprevir –brand name Ganovo, and oral antiviral used for hepatitis C in China. Ongoing Phase 4 study in China of danoprevir+ritonavir as one of 5 experimental therapies. Comparators include interferon (Pegasys 180 mcg SQ weekly), Novaferon inhalation (cytokine gene derived protein), lopinavir/ritonavir or Chinese medicine + interferon inhalation –			
T89 – Effect of T89 on improving oxygen saturation and clinical symptoms in patients with COVID-19. Open-label, randomized trial of T89 or control for up to 14 days in addition to background treatment of antiviral, antibiotic, oxygen and traditional Chinese medicine. T89 is taken twice daily for 10 days			
Aviptadil--Synthetic form of vasoactive intestinal polypeptide approved in Europe for several respiratory diseases and suggested as immunomodulator in ARDS given as titrated escalating infusion 50-150 pmol/kg/hr over 12 hours			
Umifenovir			
CD424Fc SAC-COVID - biological immunomodulator in phase II/III studies in leukemia patients with severe GVHD. Will be given as a single dose 480mg in 100 mg NS over 60 minutes in patients with severe COVID-19			
Angiotensin- (1-7) **ATCO Trial**– Phase 2/3 trial of infusion of angiotensin-(1-7) in patient with severe COVID-19 on mechanical ventilation			
Piclidenoson 2 mg po bid PO on empty stomach added to standard care in hospitalized pts with COVID			
Tradipitant ODYSSEY Phase 3 randomized double blind trial of tradipitant, a neurokinin-1 antagonist, 85mg orally BID in patients with severe or critical COVID			
IFX-1 single dose randomized open-label trial vs. standard care only in patients with severe COVID pneumonia			

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Pharmaceutical Use Outside of Approved Indications
Guidance on "Off-label" Prescribing

Department of Veterans Affairs (VA) Center for Medication Safety, Veterans Health Administration (VHA) Pharmacy Benefits Management Services VA Medical Advisory Panel and VISN Pharmacist Executives

August 2013

Executive Summary

1. Prescribing that is outside approved indications by the Food and Drug Administration (FDA) is often referred to as "off-label" use.
2. This often involves use outside of specified populations, or in different diseases or stages of diseases. Other types of off-label use may involve changes to dosing or dosing schedules or in chronology and sequence of use of pharmaceutical agents.
3. Familiarity with the evidence before using a drug off-label is important since there is heightened concern when there is little or no supporting evidence of benefit or safety in a population or for a condition.
4. When considering or reviewing off-label use, whether from an individual or institutional perspective, an evidence-based approach similar to the principles elucidated by the United States Preventive Services Task Force is recommended (see Appendix 1).
5. Evidence of benefit (and importantly, risk) should be explicitly reviewed in the context of standard therapies for the population or condition and recommendations for (or against) use should be based on the quality of evidence as well as the net benefit (potential benefits minus potential harms) [see Appendix 1]. Selective use of studies to support a position is strongly discouraged and in the event of a negative outcome, may not withstand the rigor of a thorough peer review.
6. Since off-label use occurs with non-formulary as well as formulary drugs, clinicians must be aware of their own prescribing practices. When prescribing outside of FDA indications, it is recommended that clinicians understand and follow local protocols and procedures, for example from their Pharmacy & Therapeutics (P&T) Committees. In these cases, the burden of responsibility rests with the prescriber.
7. Consultation with local VA P&T Committees is recommended for agents that do not already have established protocols for off-label use.
8. Pharmacy & Therapeutics Committees are responsible for considering effectiveness, equity, safety, and outcomes – and as a secondary point, cost – when making decisions about pharmaceuticals. As such, these Committees may approve or disapprove requests, based on the level and quality of evidence, in the context of local policies and procedures.

Background

Off-label use refers to a range of prescribing that is outside approved indications by the Food and Drug Administration (FDA). This may involve areas such as bioequivalence (e.g, generic products or modified-release dosage forms), dosing (e.g., above maximum or subtherapeutic), dosing schedules (e.g., using more often than approved), dosing regimens (e.g., using a drug approved for combination therapy as monotherapy) or chronology (e.g., using an agent as first line therapy instead of its approved second line usage). More often, off-label use refers to utilization outside of specified populations (e.g., by gender or age or weight) or in different diseases (or stages of diseases) than originally approved.

Benefits of therapies should not be assumed across populations or for conditions even when there exists plausible epidemiological evidence, biological plausibility or cohort studies – all of which contributed to use of hormone replacement therapy in women prior to the randomized trial that outlined the potential hazards [Women's Health Initiative, 2002]. With emerging drug therapies, especially, it is important that safety be addressed explicitly. A frequent assumption is that a product is as safe in one population as another; without considering possible drug-disease interactions and/or to possible lower efficacy rates. For example, beta-carotene is relatively harmless in the general population yet it appears to increase the risk of lung cancer in heavy smokers [Alpha-Tocopherol, Beta-Carotene, 1994; Omen 1996]. Hence, just as efficacy and effectiveness of a medication cannot necessarily be extrapolated to new indications or uses, the safety of pharmaceuticals should not be considered constant across diseases or populations.

In general, off-label use becomes a heightened concern when there is little or no supporting evidence of benefit or

safety in a population or for a condition. This may occur, for example, soon after a new drug is released and/or when marketing is expanding ahead of published evidence. Under these circumstances, both the risks and benefits of utilization become more difficult to gauge. Hence, new evidence concerning emerging off-label use of a drug must be viewed in the context of standard therapies for a disease or population since these often have far more data on effectiveness and safety. In some instances, older drugs may be prescribed for newer (off-label) uses and while there may be relatively reassuring data on safety, there is often little on efficacy or effectiveness for the proposed use.

Overall, thoughtful and evidence-based use of medications is good clinical practice. This is true for all medication use, whether used within or outside of approved FDA indications, especially because FDA labeling and indications depend on submissions and requests to (and from) that agency. Contemporary prescribing must also consider new evidence as well as data that may or may not have been submitted to the FDA. Also, when the FDA approves a drug, it typically considers safety in relationship to the approved indication and other therapies. For instance, when a drug is approved as a second or third alternative, or for a relatively serious medical condition, a more significant side effect profile may be acceptable even though it would not be so for a less serious situation, or for first line therapy. These issues must be kept in mind when considering and reviewing off-label use of pharmaceuticals.

Focus

The following guidance applies to issues outside of bioequivalence and modified dosing forms, for which use, unless stated otherwise for a particular drug, is generally considered standard practice.

Goals

The Center for Medication Safety in conjunction with the Pharmacy Benefits Management Services and its Medical Advisory Panel and VISN Pharmacist Executives outline below the general principles and recommendations when considering pharmaceutical use outside of approved dosing, chronology, disease or disease stage or populations.

Our intention is to offer an educational and dynamic document to assist healthcare providers, as well as Pharmacy & Therapeutics (P&T) Committees and other policymakers, to better understand and oversee "off-label" use and to use principles of evidence-based medicine, as described in Appendix 1, in reviewing such use.

General Principles

1. First and foremost, pharmaceutical prescribing should be evidence-based, whenever possible (i.e., when sufficient evidence exists for a robust review).
2. The ultimate responsibility for the safety and efficacy of off-label prescribing resides with the prescriber. He/she should be familiar with the evidence of benefit and with the safety profile before using a drug. He/she should know and understand local protocols for use of the agent or consult with local pharmacist.
3. Consultation with the VA P&T Committee is recommended for agents that do not already have established protocols for off-label use.
4. Proper assessment of evidence for off-label use should involve as comprehensive and balanced review as possible and feasible. An assessment of study quality and net benefit is sometimes necessary to fully understand safety and efficacy. Evidence should be viewed in the context of other more standard therapies. Selective use of studies to support a position is strongly discouraged and in the event of a negative outcome, may not withstand the rigor of a thorough peer review.
5. Pharmacy & Therapeutic Committees, as agents of an institution, and pharmacists can and should assist clinicians, when requested, to assure effective (and cost-effective) and safe use of medications, as substantiated by scientific evidence.
6. Clinicians may request review by Pharmacy & Therapeutics Committees for off-label use, but equally so, the P&T Committee may ask the requestor to provide literature regarding the benefit and safety for requests, as part of their review process.
7. Pharmacy & Therapeutics Committees are considered the arbiters of such matters and have the right to approve or disapprove submitted requests, based on the merit of scientific evidence and on local or national policy and procedures.

General Recommendations:

An evidence-based approach that underscores evidence assessment, such as that used by the United States Preventive Services Task Force , is recommended when prescribing or when reviewing requests for off-label use. Some pharmaceutical references summarize existing evidence (e.g., Facts and Comparisons or MICROMEDEX) and these may be helpful, depending on the circumstances. One method to provide context on risk and benefit is to assess number needed to treat (NNT) for specified end point(s) and number needed to harm (NNH) for specified adverse events. The American College of Physicians' Journal Club defines various terms and definitions, including NNT and NNH, at http://acpjc.acponline.org/shared/glossary.htm).

If a medication's efficacy or safety profile is relatively unknown or cannot be quantified, or if new data are emerging that suggest possible adverse effects that were previously unknown or unclear, then providers and overseeing Pharmacy & Therapeutics committees should be very wary of use. In certain circumstances, use may reasonably be subject to additional stipulations from P&T Committees (see under, **Other Issues**, below). As with any pharmaceutical use, on or off label, formulary and non-formulary policies, and related approvals procedures, should apply.

Note that the examples that follow should be considered illustrative and not definitive statements, since information and evidence change constantly.

1. Off-label use is generally appropriate when there exists properly conducted scientific studies of high quality and of sufficient size to firmly establish risks and benefits, (for example, see Appendix 1), for the disease and/or population. In practical terms this means a Level of Evidence I (high-grade evidence linked to a health outcome), with a substantial or moderate net benefit, that reaches a Strength of Recommendation of A (strongly recommended) or B (may be useful). Criteria for use and for approval are at the discretion of local Pharmacy & Therapeutics Committees, unless stated otherwise.

   Previously, an example would be use of spironolactone for reducing mortality in advanced systolic heart failure (level I evidence) [Pitt, 1999]. The use of spironolactone in this circumstance yielded moderate net benefit on an important health outcome and would receive a strength of recommendation of B. Recently, spironolactone received FDA approval for severe heart failure based upon these published data.

2. Off-label use may be appropriate when there exists Level II-1 (high-grade evidence linked to an intermediate outcome), or Level II-2 or II-3 evidence (moderate evidence linked to a health outcome), with small to substantial net benefit, leading to a Strength of Recommendation of B (may be useful) or perhaps C (intervention may be considered) [Appendix 1]. Typically, such a recommendation either requires multiple sources of (consistent) moderate level evidence in order to quantify the anticipated benefits and possible adverse effects of therapy or, in some cases, small randomized control trials with an important health outcome (Level II-1) to substantiate the request, though the strength of recommendation tends to be relatively weak (e.g., a "C"). Further consideration may be given if the designated use is documented in standard resources or references. These may include but are not necessarily limited to: (a) general or specialty specific textbooks, (b) standard drug references such as MICROMEDEX®, Drug Facts and Comparisons, United States Pharmacopeia Dispensing Information, or American Hospital Formulary Service Drug Information, (c) review papers from widely recognized or specialty-specific peer review journals; (d) properly conducted meta-analyses and evidence based medicine reviews (e.g., Cochrane Collaboration) or (e) locally approved guidance such as a pre-approved protocol by an institution's P&T Committee; or (f) within VA (or VA/DoD) Guidelines. Again, criteria for use and for approval are at the discretion of local Pharmacy & Therapeutics Committees, unless stated otherwise.

   An example is the use of modafinil for fatigue associated with Multiple Sclerosis (MS). Evidence of benefit has been demonstrated in four trials comprising double blinded, single blinded and open label trial methodologies. Additionally, there was no net benefit shown in three other trials. The total patient population reviewed in these seven trials was 429. Per Appendix 1, an assessment yields a Level of Evidence of II-1, with small to moderate net benefit and hence at best a recommendation of B. The use of modafinil may be considered after a trial with amantadine, which is also off label but has stronger clinical evidence.

3. Off-label use should be far more cautionary, and appropriateness is less clear, where there exists Level III evidence (no linkage to health outcomes) or Level IV (insufficient evidence) without any of the resources or references above. In considering use, there should still be some supportive evidence of net benefit available such as case reports, abstracts from national or international conferences, small studies of some scientific merit or

studies that include a selected subpopulation and where extrapolation to the population at hand may be relevant due to, for example, biological plausibility. At best, these situations give a graded recommendation of Insufficient Evidence (I). Importantly, safety should be addressed as explicitly as possible since there exists the potential to do harm. Use may also be considered under very selected circumstances, such as when no other option exists or when theoretical reasoning is compelling (for example, when an argument can be made for extrapolating results from one population to another or when based on pathogenesis of a disease). In general, providers should not utilize pharmaceuticals under these circumstances without prior P&T assessment and approval (or precedent for such). Moreover, when requests are sent to P&T, these should typically be reviewed on a case-by-case basis and be subject to one or more stipulation, as described below.

An example would be using Botulinum toxin for anal fissures; there are small randomized control trials showing improvement, but long term outcomes are not well defined, and adverse events are also reported (e.g., incontinence of stool) [Altomare, 2011].

4. Off-label use is generally not appropriate when there is no or very little substantiating evidence on a disease or an intermediate outcome for that disease. At best this represents a grade of Level I (insufficient evidence), and it is important to note that in such cases harm is always possible. Exceptions may include limited instances when, for example, there is biological plausibility for an outcome and the disease state or condition is rare or when incidence is so low as to preclude reasonable study(ies).

5. Off-label use is clearly not appropriate when available evidence suggests possible or probable harm with little benefit or when seminal studies suggest no benefit to the population or disease specified (which differs from situations when there is no or little evidence of benefit due to lack of appropriate studies).

An example would be use of gabapentin for mood disorders, a situation where early reports were promising but further studies failed to suggest substantive net benefit [Backonja, 1998]. Another example would be that benzodiazepine administration should be discouraged both in acute stress disorder and post-traumatic stress disorder, due to the lack of evidence for effectiveness and risks that outweigh potential benefits (i.e., there is evidence to suggest that benzodiazepines may actually potentiate the acquisition of fear responses and worsen recovery from trauma)[VA-DOD Guidelines].

Other Issues

1. Off-label use may be entirely appropriate in many situations, but when sufficient evidence from properly conducted randomized control trials is not available to justify efficacy/effectiveness and/or safety, additional requirements or stipulations are reasonable, at the discretion of the local P&T Committee. As a general rule, the stipulations and requirements should become more stringent as the benefits (e.g., NNT) and the harms (e.g., NNH) of therapy become more difficult to quantify. Examples of such stipulations and requirements may include:

   a. A pre-determined therapeutic trial of clinically reasonable duration with a specified follow-up period and/or specified outcome.

   b. Development of criteria for subsequent utilization and monitoring.

   c. Documentation in the medical record by the requestor or delegate that a conversation on risks and benefits has taken place with the patient (or designated caregiver, as appropriate) and that the patient or caregiver understands that the drug has not been studied and/or approved for use in the proposed manner and that he/she accepts the attendant risks. For example, "I have discussed the risks and benefits with this patient and he/she agrees with the use of this agent, even though it has not been studied and/or approved for the proposed use."

   d. Formal informed consent protocol document signed by the patient or caregiver prior to use (this protocol should be utilized rarely and generally only when there is the possibility of a life or organ threatening safety issue connected with use of a drug).

   e. Referring the matter to the local Research & Development Service as possible investigational therapy (Note that this should be a very rare occurrence. The FDA policy on referral to an institutional review board is available the following link: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm).

Appendix 1

Determining Evidence Levels and Strength of Recommendations

The following evidence grading and assessment scales are based on those used by the Joint VA/DoD Evidence Based Practice Work Group (EBPWG). This method is similar to that used by the U.S. Preventative Services Task Force. Assessments should be guided by as comprehensive a review of the available literature as possible and feasible, and not by selectively choosing or interpretating individual studies.

Further discussion of methods can be found at
http://www.uspreventiveservicestaskforce.org/methods.htm

In addition, other resources for reference and tutorials include Cochrane Collaboration,
The American College of Physicians and the University of Toronto Centre for Evidence Based Medicine.

Assessment and grading of evidence and benefit is as follows:

1. Assess overall quality of evidence using the terms shown in Table 1.
2. Assess the net benefit (benefits minus harms) "substantial," "moderate," "small," or "zero or negative" as described in Table 2.
3. Based on ratings of the overall quality of the evidence and the magnitude of net benefit, grade the recommendation using the grid in Table 3 (Level of Recommendation)

TABLE 1: Overall Quality

I	High grade evidence (I or II-1) **directly linked** to health outcome
II	High grade evidence (I or II-1) **linked to intermediate** outcome or Moderate grade evidence (II-2 or II-3) directly linked to health
III	Level III evidence or no linkage of evidence to health outcome
IV	Insufficient Evidence

Definitions

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series studies with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

TABLE 2: Net Benefit of the Intervention

Substantial	More than a small relative impact on a frequent condition with a substantial burden of suffering – or - A large impact on an infrequent condition with a significant impact on the individual patient level.
Moderate	A small relative impact on a frequent condition with a substantial burden of suffering - or - A moderate impact on an infrequent condition with a significant impact on the individual patient level.
Small	A negligible relative impact on a frequent condition with a substantial burden of suffering - or - A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or Negative	Negative impact on patients - or - No relative impact on either a frequent condition with a substantial burden of suffering - or - An infrequent condition with a significant impact on the individual patient level.

* Generally this is in comparison to established standards (and/or placebo, when there is no comparison to other

standard therapies)

TABLE 3: Determine Level of Recommendation

	The net benefit of the intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or -**
I	A	B	C	D
II	B	B	C	D
III	C	C	C	D
IV	I	I	I	D

Definitions

A Strong recommendation that the intervention is always indicated and acceptable
B Recommendation that the intervention may be useful/effective
C Recommendation that the intervention may be considered
D Recommendation that a procedure may be considered not useful / effective, or may be harmful.
I Insufficient evidence to recommend for or against the intervention

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Hydroxychloroquine/Chloroquine Safety During Off-Label Use for COVID-19

- FREQUENTLY ASKED QUESTIONS -

MARCH 30, 2020 (AMENDED APRIL 23,2020)

VA PHARMACY BENEFITS MANAGEMENT SERVICES [PBM] AND CENTER FOR MEDICATION SAFETY [VAMedSAFE]

Q: Is hydroxychloroquine (HCQ) or chloroquine (CQ) approved for treatment of the 2019 novel Coronavirus (COVID-19)?

A: No. No therapy is currently FDA-approved for prophylactic or post-exposure treatment of the 2019 novel Coronavirus (COVID-19). HCQ is indicated for the prophylaxis and treatment of malaria, as well as the treatment of autoimmune diseases (rheumatoid arthritis and systemic lupus erythematosus).[1] CQ is indicated for the treatment of malaria and amebiasis.[2]

Q: What is the mode of action of HCQ/CQ in the treatment of COVID-19?

A: CQ and HCQ are 4-aminoquinoline drugs. HCQ is a derivative of CQ. Due to similar structures, it is suggested that HCQ and CQ inhibit virus infection by elevating endosomal pH required for virus/cell fusion and disrupting the glycosylation of cellular receptors (i.e., ACE2) needed for virus-receptor binding. Activity of CQ and HCQ against COVID-19 was discovered in vitro; HCQ was found to be more potent in activity than CQ in vitro.[3-6]

Q: What data are available for the use of HCQ/CQ in the treatment of COVID-19?

A: Evidence from peer-reviewed randomized clinical trials is lacking. Limited efficacy findings are available at: VHA PBM Information on Investigational and off-label Treatment Options of COVID-19.[7] Further studies are needed.

Q: What are the options for use of HCQ/CQ in the treatment of COVID-19 within the VA?

A: Ideally, use of treatments for COVID-19 would be in the context of a clinical trial. However, in the absence of such a trial, considerations for off-label use should occur using the best available information, in consultation with Infectious Diseases and/or other facility designated experts, and only AFTER evaluating the potential benefits and risks associated with the treatment, customized to the needs of the patient. Discussion of these risks/benefits should be in consultation with the patient, family, and in keeping with the PBM Document entitled: Pharmaceutical Use Outside of Approved Indications Guidance on "Off-Label" Prescribing (August 2013).[7]

Q: What are the dosing considerations associated with the use of HCQ/CQ in the treatment of COVID-19?

A: Optimal dosing and duration of HCQ/CQ for COVID-19 are unknown. Therapeutic index is narrow; the toxic dose is as little as 3-5 times the therapeutic dose. An overdose of HCQ/CQ can cause acute toxicity and death.[1-2]

- The following dosing for off-label treatment of COVID-19 has been studied:
  - HCQ: 400mg twice daily for 1 day, followed by 200mg twice daily x 4 more days.
    Note: if given with azithromycin, 200mg three times daily for 10 days would also be appropriate.
  - CQ: 500mg twice daily for 10 days.
- Compared to CQ, HCQ is preferred based on improved in vitro activity and safety but CQ is an appropriate option if HCQ is not available.
- HCQ/CQ tablets may be crushed to prepare suspensions for NG/OG administration.[8]

See Table 1 (page 2) for additional dosing considerations.

Q: Are there any contraindications against the use of HCQ or CQ?

A: Yes - pre-existing retinopathy of the eye and known hypersensitivity to 4-aminoquinoline compounds.[1-2]

Q: What are the potential risks associated with HCQ/CQ use?

A: Both CQ and HCQ have known safety profiles with side effects that include, but are not limited to:[1-2]

- Cardiac risks: QT prolongation and arrhythmia
- Neuro/psychiatric risks: seizures, delirium, anxiety, depression, psychosis
- Hypersensitivity reactions: rash/pruritis, erythema multiforme
- Hypoglycemia: sometimes profound
- Hematologic: hemolytic anemia with G6PD deficiency
- Gastrointestinal side effects: nausea, abdominal pain and diarrhea
- Possibility that HCQ/CQ may worsen long term outcomes due to immune modulating and anti-inflammatory properties of CQ in vivo.[9]

See Table 2 (page 2) for additional details. While some risks would only be expected with chronic therapy (i.e., cardiomyopathy, retinopathy), safety in this population (i.e., sick, possibly critically-ill patients) HAS NOT BEEN ESTABLISHED.

Q: What are the monitoring recommendations for cardiotoxicity associated with the use of HCQ/CQ within the VA?

A: QT should be monitored prior to initiation and drug avoided if QT > 490 msec. Ideally patients should be on telemetry, and if tele QTc is concordant to EKG QTc, telemetry can be used for further QTc monitoring.

- For patients not on telemetry, a repeat EKG should be taken after starting HCQ/CQ and considered daily if risk factors.
- Discontinue all other QT prolonging agents, if possible.
- If QTc increases by > 50 msec, or absolute QTc > 500 msec, discontinuation should be strongly considered.
- Of note, other modifiable risk factors (K+, Mg++) should be monitored and controlled for.
- **Azithromycin may prolong the QTc and has been shown to increase the risk of sudden cardiac death.**[8]

Q: What drugs should be reviewed for interactions prior to administration of HCQ/CQ?

A: A comprehensive medication review should assess for the following concurrent medications (among others): medications that prolong the QT interval, (including but not limited to Class 1A, 1C, III antiarrhythmics, certain antidepressants, antipsychotics, fluoroquinolones, macrolides, 5-HT3 receptor antagonists) due to increased risk of QT prolongation; drugs metabolized by CYP2D6 (i.e., beta-blockers, antipsychotics, antidepressants) as HCQ/CQ inhibits CYP2D6 and may increase levels of these drugs; antacids due to the potential to reduce the activity of HCQ/CQ (administration should be separated by 4 hours).[1-2] See Table 3 (page 2) for additional details.

Table 1. Dosing considerations for the use of hydroxychloroquine or chloroquine. [1-2]

	HYDROXYCHLOROQUINE (PLAQUENIL®) | [HCQ]	CHLOROQUINE (ARALEN®) | [CQ]
DOSING CONSIDERATIONS	• Daily doses should not exceed 6.5 mg (salt form)/kg ideal (lean) body weight. • Using absolute body weight could result in an overdosage. • Exceeding the recommended daily dose increases risks of retinal toxicity and cardiac arrhythmias. • One 200 mg tablet is equivalent to 155 mg base.	• Daily dose of chloroquine phosphate should not exceed 2.3 mg/kg of actual body weight. • Exceeding the recommended daily dose increases risks of retinal toxicity and cardiac arrhythmias. • Each 500 mg tablet contains the equivalent of 300 mg base.
OVERDOSE	• Symptoms may occur within 30 minutes and include: headache, drowsiness, visual disturbances, cardiovascular collapse, hypokalemia and convulsions, rhythm and conduction disorders, including QT interval prolongation, torsade de pointes, ventricular tachycardia, ventricular fibrillation, width-increased QRS complex, PR interval prolongation, bradyarrhythmias, nodal rhythm, atrioventricular block, followed by sudden potentially fatal respiratory and cardiac arrest. • Treatment is symptomatic and supportive with observation (e.g., ECG monitoring). The ECG may reveal atrial standstill, nodal rhythm, prolonged intraventricular conduction time, and progressive bradycardia leading to ventricular fibrillation and/or arrest.	• Symptom onset possible within minutes, including nausea, vomiting, headache, drowsiness, visual disturbances, cardiovascular collapse, convulsions, hypokalemia, rhythm and conduction disorders including QT prolongation, torsade de pointes, ventricular tachycardia and ventricular fibrillation, followed by sudden potentially fatal respiratory and cardiac arrest. Extrapyramidal disorders may occur. • Treatment is symptomatic with immediate evacuation of the stomach by emesis or gastric lavage followed by activated charcoal. Care should include cardio-respiratory and hemodynamic support, monitoring of potassium along with management of arrhythmias and convulsions, as necessary.

Table 2. Risks associated with the use of hydroxychloroquine or chloroquine and precautions to consider. [1-2]

SYSTEM	RISK	PRECAUTION
Cardiovascular	• Cardiomyopathy (Life-threatening and fatal) • Electrocardiogram (ECG) Changes and Potential for Cardiac Arrhythmias (Serious and fatal outcomes, including ventricular arrhythmias, heart blocks, ventricular fibrillation, QTc prolongation, and torsade de pointes) • The magnitude of QT, PR or QRS prolongation is dose-dependent.	• Not recommended in patients with baseline QTc prolongation (e.g., congenital or acquired Long QT Syndrome), second-or third-degree atrioventricular block. • Electrolyte imbalances (e.g. hypokalemia/hypomagnesemia/hypocalcemia) must be corrected prior to use. • Caution in patients with risk factors for torsade de pointes, including, but not limited to: female gender; age ≥ 65 years; baseline prolongation of the QT/QTc interval; presence of genetic variants affecting cardiac ion channels or regulatory proteins, especially congenital long QT syndromes; family history of sudden cardiac death at <50 years of age; cardiac disease (e.g., myocardial ischemia or infarction, congestive heart failure, cardiomyopathy, conduction system disease); history of arrhythmias; electrolyte disturbances or conditions leading to electrolyte disturbances (e.g., persistent vomiting, eating disorders); bradycardia; acute neurological events (e.g., intracranial or subarachnoid hemorrhage, stroke, intracranial trauma); diabetes mellitus; autonomic neuropathy • Concomitant use with other QTc, PR or QRS interval prolonging drugs should be avoided or undertaken with particular caution. • If cardiotoxicity is suspected, discontinue use promptly.
Endocrine/Metabolism	Severe hypoglycemia (+/- antidiabetic drugs)	Concomitant antidiabetic therapy may enhance hypoglycemic effects. Closely monitor glucose while on therapy. Lower dose of antidiabetic drugs/insulin as needed
Hematologic	Bone marrow depression	Caution in patients with blood disorders or glucose-6-phosphate dehydrogenase deficiency due to hemolytic anemia (less concern with HCQ than CQ), leukopenia.
Hepatic	Abnormal LFTs and fulminant hepatic failure	Caution in hepatic disease or alcoholism, in whom a reduction in dosage may be necessary, or in conjunction with known hepatotoxic drugs.
Neurologic/Psychiatric	Muscular weakness, extrapyramidal reactions, suicidal behavior/ideation, seizures	Caution or avoid in patients with history of seizures.
Ophthalmologic	Irreversible retinal damage	Retinal toxicity is largely dose-related.
Renal	Potential for adverse events with renal impairment due to long half-life	Caution in renal dysfunction.
Skin	Exacerbation of psoriasis or porphyria; Erythema multiforme (uncommon) and rash/pruritis (common)	Not recommended in psoriasis or porphyria due to possible exacerbation. Recommend discontinuation in setting of severe skin reactions.

Table 3. Drugs that may interact with hydroxychloroquine or chloroquine. [1-2]

DRUGS	INTERACTION
CYP2C8 and CYP3A4 inhibitors (i.e., ketoconazole, itraconazole, erythromycin, aprepitant, fluconazole, clopidogrel, teriflunomide, letermovir)	HCQ/CQ is a **substrate of CYP2C8, 3A4** - Co-administration may increase HCQ/CQ levels.
Drugs metabolized by CYP2D6 (i.e., beta-blockers, antipsychotics, antidepressants)	HCQ/CQ **inhibits CYP2D6** - May increase levels of drugs metabolized by CYP2D6.
Antacids	May reduce absorption of HCQ/CQ. Administer 4-hours apart.
Antidiabetic Drugs and Insulin	May enhance hypoglycemic effect; decrease in dose of antidiabetic drugs/insulin may be required.
Cyclosporine	Levels may increase since HCQ/CQ **inhibits CYP3A4.**
Digoxin	May result in increased serum digoxin levels; monitor digoxin levels closely in concomitant treatment.
Drugs that prolong the QRS and/or QT interval and other arrhythmogenic drugs including, but not limited to, Class IA, IC and III antiarrhythmics; certain antidepressants, antipsychotics, and anti-infectives (i.e., fluoroquinolones, macrolides); domperidone; 5-hydroxytryptamine (5-HT)3 receptor antagonists; kinase inhibitors; histone deacetylase inhibitors beta-2 adrenoceptor agonists	Cardiotoxic effects. *Note:* **Azithromycin may prolong the QTc and has been shown to increase the risk of sudden cardiac death.** Documented in outpatients (not in context of COVID); risk was greatest in those with the highest baseline CV. **Overuse can also lead to C.difficile and antibiotic resistance.**
Drugs that affect electrolytes including, but not limited to, loop, thiazide, and related diuretics, laxatives and enemas, amphotericin B, high dose corticosteroids, and proton pump inhibitors	Cardiotoxic effects.
Tamoxifen/Drugs known to induce retinal toxicity	Concomitant use is not recommended due to retinal toxicity.

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COVID-19 SUPPLEMENT | VOLUME 10 | MAY 2020

MEDICATION SAFETY IN SECONDS

A MONTHLY PUBLICATION FROM VA MEDSAFE:
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER

Helping to achieve safe medication use

REMDESIVIR: EMERGENCY USE AUTHORIZATION FOR POTENTIAL COVID-19 TREATMENT; LIMITED DATA AVAILABLE

FDA Issues EUA

FDA has issued an emergency use authorization (EUA) for the investigational antiviral remdesivir in patients with COVID-19. Under this EUA, the unapproved product can be administered by health care providers to treat hospitalized patients with suspected or laboratory-confirmed COVID-19 that is severe. Severe disease is defined as low blood oxygen levels (<94%), the need for oxygen therapy, or intensive respiratory support (i.e., mechanical ventilation or extracorporeal membrane oxygenation [ECMO]).

The EUA was based on a clinical trial shown to shorten the time to recovery in some patients. The ACTT trial (Adaptive COVID-19 Treatment Trial) is an ongoing phase 3, double-blind, placebo-controlled trial of hospitalized patients with severe COVID-19 pneumonia, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID). Patients must have infiltrates on X-ray, require oxygen or ventilatory support or have room air oxygen saturation less than 94%. Preliminary results suggest that patients who received remdesivir had a 31% faster time to recovery than those who received placebo (11 days for patients treated with remdesivir versus 15 days for those who received placebo, p<0.001). Results also indicate numerically lower mortality without statistical significance (8.0% for the remdesivir group versus 11.6% for placebo, p=0.059). Treatment in this study consists of 200 mg of remdesivir on the first day of enrollment followed by 100 mg per day for nine subsequent days of hospitalization or placebo. Final results including baseline demographics of the groups and details of the primary and secondary analyses are still forthcoming. Based on these data, a new NIAID trial, named ACTT2, will look at remdesivir alone versus remdesivir plus baracitinib to assess whether adding an anti-

(continued on page 3)

NEWSWORTHY...

from the pbm

- VHA PBM Information on investigational and off-label treatment of COVID-19 document - 05/07/2020
- Hydroxychloroquine/Chloroquine and Risk of Use Outside Hospital or Clinical Trial Settings - National PBM Bulletin - 04/24/2020
- HCQ and CQ Safety for COVID-19 Frequently Asked Questions AMENDMENT- 04/23/2020 – FAQ Sheet AMENDMENT

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IN THIS ISSUE:

VA PHARMACY BENEFITS MANAGEMENT SERVICES (PBM)

PBM maintains VA's national drug formulary, as well as promotes, optimizes, and assists VA practitioners with the safe and appropriate use of all medications.

VA CENTER FOR MEDICATION SAFETY (VA MedSAFE)

VA MedSAFE performs pharmacovigilance activities; tracks adverse drug events (ADEs) using spontaneous and integrated databases; enhances education and communication of ADEs to the field; and promotes medication safety on a national level.

EDITOR-IN-CHIEF

Marie Sales, Pharm.D.

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NEWSWORTHY...

from the fda

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COVID-19 DISEASE

Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Additional Safety Protections Pertaining to SARS-CoV-2 and COVID-19

03/23/2020

Studies suggest that SARS-CoV-2 ribonucleic acid (RNA) and/or SARS-CoV-2 virus can be present in stool of infected individuals.[1-3] FDA warns that use of fecal microbiota for transplantation (FMT) to treat Clostridium difficile (C. difficile) infection in patients who have not responded to standard therapies may have the potential to transmit SARS-CoV-2, although the risk of such transmission is unknown.[4] To address the risk, stool used for FMT should have been donated before December 1, 2019. If stool used for FMT is donated after December 1, 2019, additional protective measures to take include:

- Donor screening with questions directed at identifying donors who may be currently or recently infected with SARS-CoV-2;
- Testing donors and/or donor stool for SARS-CoV-2, as feasible;
- Development of criteria for exclusion of donors and donor stool based on screening and testing; and
- Informed consent that includes information about the potential for transmission of SARS-CoV-2 via FMT, including FMT prepared from stool from donors who are asymptomatic for COVID-19.

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Information Pertaining to Additional Safety Protections Regarding Use of Fecal Microbiota for Transplantation - Screening Donors for COVID-19 and Exposure to SARS-CoV-2 and Testing for SARS-CoV-2

04/09/2020

A previous safety alert addressed the potential risk of transmission of SARS-CoV-2 virus via fecal microbiota for transplantation (FMT). At that time, FDA determined the need for additional protections for any use of FMT, whether under an Investigational New Drug Application (IND) on file with the FDA or under FDA's enforcement discretion policy. FDA is providing an update on these additional protections, which includes no clinical use of FMT product manufactured from stool donated on or after December 1, 2019, until the following measures are implemented:

1. Stool donor screening.
   - Assess whether the donor was diagnosed with laboratory-confirmed SARS-CoV-2 infection; experienced symptoms of COVID-19 (e.g., fever, cough, shortness of breath) not explained by another diagnosis; or was exposed to a suspected or confirmed case of COVID-19 or SARS-CoV-2 infection since December 1, 2019.
   - If SARS-CoV-2 infection or exposure is suspected or confirmed, exclude donor from further donations and exclude from clinical use any FMT product manufactured from stool donated by the affected donor beginning 4 weeks prior to the date of infection/exposure.
2. Testing stool donation or stool donor for SARS-CoV-2 virus or RNA.
   - Testing approaches might include: upper respiratory specimens (e.g., nasal swabs) or other specimens (e.g., rectal swabs or stool donations).
   - If SARS-CoV-2 is detected, exclude donor from further donations and exclude from clinical use any FMT product manufactured from stool donated by the affected donor beginning 4 weeks prior to the first positive test.
3. As part of the informed consent process, communicate to the FMT recipient that:
   - Healthy, asymptomatic stool donors may potentially be infected with SARS-CoV-2;
   - Testing approach and other strategies are used to mitigate the risk of SARS-CoV-2 transmission; and
   - Limitations of testing and risk mitigation strategies.

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REMDESIVIR: EMERGENCY USE AUTHORIZATION FOR POTENTIAL COVID-19 TREATMENT; LIMITED DATA AVAILABLE

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inflammatory agent to the remdesivir regimen can provide additional benefit for patients.

Evidence in the literature on the use of remdesivir for treatment of COVID-19 is limited. An uncontrolled compassionate use trial of the drug observed clinical improvement in 36 of 53 patients (68%); 25 patients (47%) were discharged; and 7 patients (13%) died. The most common adverse events were increased hepatic enzymes, diarrhea, rash, renal impairment, and hypotension. However, this study lacked a control group making drug effect difficult to ascertain. Findings from a placebo-controlled trial in China of 237 patients showed remdesivir was not associated with statistically significant clinical benefits in the time to clinical improvement, mortality, or time to clearance of virus in patients with serious COVID-19 compared with placebo. Adverse events were reported in 66% of patients in the remdesivir group, of which the most commonly reported included constipation, hypoalbuminemia, hypokalemia, anemia, thrombocytopenia, and increased total bilirubin. Overall, serious adverse events were lower in remdesivir patients compared to those receiving placebo. Frequency of elevated transaminases appeared less with remdesivir (5%) than with placebo (12%). Rash and thrombocytopenia occurred with at least 4% greater incidence with remdesivir than placebo. However, more remdesivir patients than placebo patients discontinued because of adverse events (i.e., anorexia, nausea, and vomiting; aminotransferase or bilirubin increases; and worsened cardiopulmonary status). Of note, this trial was underpowered since sample size was not reached which led to early termination.

Additional preliminary data from the manufacturer includes an open-label, Phase 3 SIMPLE trial evaluating 5-day and 10-day dosing durations of remdesivir in 397 hospitalized patients with severe COVID-19 disease. Data did not show a difference in clinical improvement between a 5-day and a 10-day treatment course. Patients included had evidence of pneumonia and reduced oxygen levels that did not require mechanical ventilation upon study entry. The time to clinical improvement for 50% of patients was 10 days in the 5-day treatment group, and 11 days in the 10-day treatment group. More than half of patients in both treatment groups were discharged from the hospital by Day 14 (5-day: 60.0%, n=120/200 vs. 10-day: 52.3% n=103/197; p=0.14). At Day 14, 64.5% (n=129/200) of patients in the 5-day treatment group and 53.8% (n=106/197) of patients in the 10-day treatment group achieved clinical recovery. The most common adverse events occurring in approximately 10% of patients in the 5-day (n=200) and 10-day (n=197) treatment groups were nausea (10.0% [n=20] versus 8.6%, [n=17], respectively) and acute respiratory failure (6.0% [n=12] versus 10.7% [n= 21], respectively). Grade 3 or higher liver enzyme (ALT) elevations occurred in 7.3% (n=28/385) of patients, with 3.0% (n=12/397) of patients discontinuing remdesivir treatment due to elevated liver tests. An expansion up to 5,600 patients is in progress, including patients on mechanical ventilation. An exploratory analysis suggested that patients who received remdesivir within 10 days of the start of symptoms appeared to derive the most benefit. A second SIMPLE trial is ongoing to evaluate the safety and efficacy of the same dosing regimens of remdesivir plus standard of care compared with standard of care alone in 1,600 patients with moderate disease.

Mandatory Requirements for Remdesivir Administration Under EUA:

Under the EUA, health care facilities and health care providers are required to:

- Ensure awareness of the letter of authorization and the conditions for remdesivir emergency use, which consist of treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in adults hospitalized with severe disease defined as patients with an oxygen saturation (SpO2) ≤ 94% on room air or requiring supplemental oxygen or requiring invasive mechanical ventilation or requiring ECMO.
- Provide authorized Fact Sheets to providers and to patients/caregivers, respectively, through appropriate means.
  - As part of the current EUA, FDA requires that the manufacturer provide fact sheets about remdesivir for health care providers and patients, which include information on potential adverse events such as increased levels of liver enzymes and infusion-related reactions (hypotension, nausea, vomiting, diaphoresis, and shivering) as well as dosing.
  - Fact sheets are available at the following links:
    - ⇒ https://www.fda.gov/media/137566/download Fact Sheet for Health Care Providers, Emergency Use Authorization (EUA) of Remdesivir (GS-5734™)
    - ⇒ https://www.fda.gov/media/137565/download Fact Sheet for Patients and Parent/Caregivers, Emergency Use Authorization (EUA) of Remdesivir for Coronavirus Disease 2019 (COVID-19)
- Communicate to patients and/or caregivers information consistent with the "Fact Sheet for Patients and Parents/Caregivers" prior to the patient receiving remdesivir. Documentation in the patient's medical record must confirm that the patient/caregiver was:
  - Given the Fact Sheet for Patients and Parents/Caregivers.
  - Informed of alternatives to receiving remdesivir and the risks and benefits of those alternatives.
  - Notified that FDA has authorized the emergency use of remdesivir, which is not an FDA approved drug.

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Getting the most from our safety surveillance

FDA CAUTIONS AGAINST USE OF HYDROXYCHLOROQUINE OR CHLOROQUINE FOR COVID-19 OUTSIDE OF THE HOSPITAL SETTING OR A CLINICAL TRIAL DUE TO CARDIAC RISK

FDA cautions that hydroxychloroquine (HCQ) or chloroquine (CQ), when used for COVID-19, should be limited to clinical trial settings or in-hospital use for certain patients under the Emergency Use Authorization (EUA). FDA became aware of increased use of HCQ and CQ through outpatient prescriptions. FDA reviewed case reports of serious cardiac adverse events and death in patients with COVID-19 receiving HCQ or CQ, either alone or combined with azithromycin or other QT prolonging medicines from the FDA Adverse Event Reporting System, the published medical literature, and the American Association of Poison Control Centers National Poison Data System. These adverse events occurred in hospital and outpatient settings and include QT interval prolongation, ventricular tachycardia and ventricular fibrillation, and in some cases, death associated with the use of HCQ or CQ to treat or prevent COVID-19.

HCQ and CQ have not been proven to be safe and effective for treating or preventing COVID-19. Recent studies suggest a lengthening effect on QT interval with the combined use of HCQ and azithromycin. Close supervision is strongly recommended due to potential for QT prolongation, other serious side effects, and drug-drug interactions with QT-prolonging medicines. Patients taking HCQ or CQ for FDA-approved indications to treat malaria or autoimmune conditions should continue taking their medicine as prescribed; the benefits outweigh risks at the recommended doses for these conditions.

Last month, VA PBM/MedSAFE issued a National PBM Bulletin addressing FDA's warning against use of hydroxychloroquine (HCQ) and chloroquine (CQ) for COVID-19 outside of the hospital or clinical trial settings (i.e., outpatient use unless in a clinical trial) due to risk of cardiotoxicity. Recommendations include:

- Use of HCQ/CQ for COVID-19 **should** be in the context of a clinical trial, **especially in unsupervised outpatient settings**. In the absence of such a trial, off-label use in hospitalized patients should occur using the best available information, **only AFTER** consultation with Infectious Diseases and/or other facility designated experts, **AND AFTER** evaluating the potential benefits and risks associated with the treatment, customized to the needs of the patient. Discussion of these risks/benefits should be in consultation with the patient, family, and in keeping with the PBM Document entitled: Pharmaceutical Use Outside of Approved Indications Guidance on "Off-Label" Prescribing (August 2013).
- Providers should monitor QTc at baseline and continue monitoring after start of HCQ or CQ.
- Providers should report any adverse drug events with the use of HCQ/CQ alone or those caused by drug-drug interactions by entering the information into CPRS' Allergies/Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail).
- Additional safety information and monitoring recommendations for HCQ or CQ have been addressed in a "Frequently Asked Questions" document, which is available at: https://vaww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/FAQ%20SHEETS/HCQ%20and%20CQ%20%20Safety%20for%20COVID-19%20Frequently%20Asked%20Questions_Amendment_FINAL.pdf .

For further details, please refer to the National PBM Bulletin issued on April 24, 2020.

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FDA Drug Safety Communication. FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or . Accessed 4/24/2020.

GENERAL COVID –19 RESOURCES

Click on links below for more information:

- CDC Information on COVID-19 Disease for Healthcare Professionals
- CDC Clinical Care Information for Healthcare Professionals Regarding COVID-19
- CDC Information on Therapeutic Options for COVID-19 Patients
- World Health Organization Interim Guidance for Clinical Management of Severe Acute Respiratory Infection When COVID-19 is Suspected
- National Institutes of Health COVID-19 Treatment Guidelines
- Guidelines from the Infectious Diseases Society of America
- The American Society of Health-System Pharmacists evidence table of COVID-19 treatments

COVID-19 ORD NOTICES & GUIDANCE

VA Office of Research and Development (ORD) resources on COVID-19 are available at:

https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19/SitePages/ORD-Communications.aspx

This SharePoint site contains information and resources for VA research administrators, investigators and staff. Content continues to be updated as new information emerges. The direct link is only accessible internally within VA.

Helping to achieve safe medication use

REMDESIVIR: EMERGENCY USE AUTHORIZATION FOR POTENTIAL COVID-19 TREATMENT; LIMITED DATA AVAILABLE

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- Advised that the patient or parent/caregiver has the option to accept or refuse remdesivir.
- Counselled on the significant known and potential risks and benefits of remdesivir, and the extent to which such risks and benefits are unknown.

- Monitor renal and hepatic parameters in accordance to the Fact Sheet for Health Care Providers:
  - Determine eGFR;
  - Hepatic laboratory testing in all patients prior to starting remdesivir and daily while receiving remdesivir.
- Track serious adverse events potentially associated with remdesivir use and report these to FDA in accordance with the Fact Sheet for Healthcare Providers.
  - The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and adverse events (death, serious adverse events) considered to be potentially related to remdesivir occurring during remdesivir treatment within 7 calendar days from the onset of the event.
  - The reports should include unique identifiers and the words "Remdesivir under Emergency Use Authorization (EUA)" in the description section of the report.
  - Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" a statement "Remdesivir under Emergency Use Authorization (EUA)."
  - Serious Adverse Events are defined as: death; a life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; a congenital anomaly/birth defect; a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.
- Through a process of inventory control, maintain records regarding:
  - the dispensed authorized remdesivir (i.e., lot numbers, quantity, receiving site, receipt date);
  - product storage;
  - patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).
- Ensure that any records associated with this EUA are maintained until notified by Gilead and/or FDA. Such records will be made available to Gilead, HHS, and FDA for inspection upon request.

In addition to the above, providers should continue to report any adverse drug events with the use of remdesivir by entering the information into CPRS' Allergies/Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or by mail). Reporting can help to identify serious and unexpected adverse events that have not been previously reported with remdesivir use given the limited experience with remdesivir at the recommended dose.

VA Distribution of Remdesivir Under EUA:

VA received a centralized supply of remdesivir and has been able to accommodate all requests for product to date. For sites that have patients who meet the EUA criteria for use of remdesivir, a patient specific order, which will be sent by UPS overnight, can be entered at the following link: https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/COVID/Lists/ROF/AllItems.aspx .

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Office of Electronic Health Record Modernization (OEHRM)
Action Plan

OIG Draft Report: Audit of VA's Infrastructure Readiness Efforts for the Electronic Health Record Modernization Program, Project Number 2019-08980-R9-0001

Date of Draft Report: February 13, 2020

Recommendations/ Actions	Status	Completion Date

Recommendation 1: Establish an infrastructure readiness schedule for future deployment sites that incorporates lessons learned from the DOD.

OEHRM Comments: Concur

OEHRM has a deployment schedule which includes the infrastructure readiness schedule. This schedule incorporates lessons learned from DOD (e.g. completing key infrastructure at least 6 months early and utilizing Cerner's backend printing functions). The deployment schedule was developed and will be updated to incorporate changes experienced during OEHRM's Initial Operating Capability (IOC). OEHRM has and will continue to coordinate with VHA and OIT to provide a unified schedule for future deployments based on the scheduled enterprise and site level assessments.

OEHRM considers Recommendation 1 completed and requests that OIG close the recommendation.

OEHRM Response 6/29/20: No change since last response.

Recommendation 2: Reassess the enterprise-wide deployment schedule to ensure projected milestones are realistic and achievable, considering the time needed for facilities to complete infrastructure upgrades.

OEHRM Comments: Concur

OEHRM has a deployment schedule, which will be updated to incorporate VA lessons learned during OEHRM's deployment. OEHRM has and will continue to coordinate with VHA and OIT to provide a unified schedule for future deployments, which incorporate VHA's agreed upon schedule for completing the required infrastructure upgrades.

OEHRM considers Recommendation 2 completed and requests that OIG close the recommendation.

OEHRM Response 6/29/20: No change since last response.

Recommendation 3: Implement tools to comprehensively monitor the status and progress of medical devices at the enterprise level.

OEHRM Comments: Concur

OEHRM developed and implemented tracking tools to effectively monitor infrastructure readiness at Mann-Grandstaff. OEHRM uses these tools to provide weekly updates of VHA Capital Improvement projects, room-by-room updates, and near real-time monitoring of deployment and imaging of computers through the VA Information Central Analytics Metrics Platform (ICAMP) system. OEHRM will continue expanding these dashboards and oversight mechanisms to more actively monitor areas like physical security and provide a better national view. OEHRM is also implementing tools to comprehensively monitor the status and progress of medical devices at the enterprise level. OEHRM plans to expand monitoring to existing VHA sites and VISN level monitoring mechanisms for medical devices which are being assessed for how they will be supporting national deployment.

OEHRM considers Recommendation 3 completed and requests that OIG close the recommendation.

OEHRM Response 6/29/20: No change since last response.

Recommendation 4: Standardize infrastructure requirements in conjunction with VHA and the OIT and ensure those requirements are disseminated to all necessary staff.

OEHRM Comments: Concur

OEHRM is collaborating with VHA and OIT to ensure a successful Go-Live. Collectively OEHRM, VHA, and OIT created the following:

- Site Infrastructure Requirements (to specify the required infrastructure);
- Site Self-Assessment (to identify infrastructure needs/deficiencies in advance of Go-Live);
- Site Infrastructure Playbook (to identify the steps a facility would need to take for a successful Go-Live); and
- Installation project monitoring tools (to create a standard and repeatable process for infrastructure upgrades).

OIT and VHA have also incorporated the above standards and requirements into their infrastructure standards. For example, VA is in the process of updating their Technical Information Library (TIL) for structured cabling to follow the latest ANSI-TIA standard. Similarly, OIT updated their computer specifications with the OEHRM specification for future technology refreshes in the enterprise.

OEHRM considers Recommendation 4 completed and requests that OIG close the recommendation.

OEHRM Response 6/29/20: No change since last response.

Recommendation 5: Evaluate physical infrastructure for consistency with OEHRM requirements and monitor completion of those evaluations.

OEHRM Comments: Concur

OEHRM is working with VHA, OIT, and Local Facilities to create a framework for validating physical infrastructure. This validation includes a facility confirmation memo that verifies site requirements are met; VHA certification that construction projects are complete; and validation from OIT that End User Devices (EUDs) are imaged and installed.

ICAMP provides real time updates to End User Devices and VHA provides monthly updates to capital improvement projects.

Status: In process Target Completion Date: March 2021

OEHRM Response 6/29/20: OEHRM will provide an infrastructure RACI in the next update of the Site Infrastructure Requirements, which will list all infrastructure components to be validated once upgrades are complete.

Recommendation 6: Fill infrastructure-readiness team vacancies until optimal staffing levels are attained.

OEHRM Comments: Concur

OEHRM TIO currently has two of six positions filled in Infrastructure Readiness with another in active recruitment. Additionally, one staff has been detailed to support infrastructure, as well as a team of 19 contractors. In the newest proposed organizational chart, TIO has requested an additional six staff for Infrastructure Readiness, with an emphasis on construction and project management.

Additionally, a team of four staff within VHA has also been stood up to manage capital improvements; they will have a direct line to VHA/VISN/VAMC leadership. Three of those four positions have been onboarded since August 2019 and the other Full Time Employee (FTE) is going through screening and background checks before being onboarded.

Status: In process Target Completion Date: March 2021

OEHRM Response 6/29/20: OEHRM continues to search and hire government employees to meet the staffing need. A detailee was extended, and OEHRM will continue to use contractor positions, along with OIT resources, to meet the need.

Recommendation 7: Ensure physical security assessments are completed and addressed at future electronic health record deployment sites.

OEHRM Comments: Concur

The Office of Security & Preparedness (OSP) is responsible for all physical and logical security at VA. OEHRM has worked with OSP on many aspects of logical security and some aspects of physical security. Additionally, OEHRM and VHA have incorporated elements of physical security into the planning and assessment documents for future facilities. These assessment and planning documents are:

(1) Site Infrastructure Requirements
(2) Site Infrastructure Playbook, and
(3) installation project monitoring tools.

OEHRM will also reassess these planning and assessment documents with VHA to ensure and validate they incorporate the requisite physical security assessments and planning for future deployment sites.

OEHRM considers Recommendation 7 completed and requests that OIG close the recommendation.

OEHRM Response 6/29/20: No change since last response.

Recommendation 8: Ensure all access points to physical infrastructure are secured and inaccessible to unauthorized individuals.

VAMC Director Comments: Concur

Mann-Grandstaff VA Medical Center leadership recognizes the importance of the physical security of the electronic health record infrastructure and will expeditiously resolve all physical security issues identified in the OIG audit.

We are working diligently to address the security issues identified in the draft report (manhole cover, equipment racks and the dumbwaiter door) and anticipate having these security issues resolved before Go-Live.

Status: In process Target Completion Date: Go-Live

OEHRM Response 6/29/20:
1. The dumbwaiter security enhancement work was completed March 13, 2020.
2. The Pharmacy Network equipment and rack was relocated and verified operational on May 14, 2020.
3. The manhole security enhancement work was completed on May 28, 2020.

FY 20 COVID-19 Obligations/Expenses	Date of Transaction	Transaction #	Type of Funds
COVID-19 VVC **Provider** Equipment	3/12/2020	776-20-2-9201-0134	160
COVID-19 **Patient** IPAD Tablet	3/12/2020	776-20-2-9201-0135	160
COVID-19 Digicert SSL Certificates	3/16/2020	776-20-2-9201-0137	160
COVID-19 MOU Val Rivish	3/18/2020	MOU: Sta 664 Phoenix, A	160
COVID-19 NTTHD 24/7 Addtl Staff - OPTIONAL TAS	3/24/2020	776-20-2-9201-0160	160
COVID-19 **Provider** iPad/Accessories	3/25/2020	776-20-2-9201-0161	160
COVID-19 **Patient** IPAD Tablet	4/6/2020	776-20-3-9580-0207	160
COVID-19 Telehealth Systems and Applications Rel	4/7/2020	776-20-3-9201-0214	160
COVID-19 **PROVIDER** Apple iPad	4/16/2020	776-20-3-9202-0002	160
COVID-19 **PATIENT** Apple iPad	4/16/2020	776-20-3-9202-0003	160
COVID-19 **PROVIDER** DELL 22 Monitor	4/16/2020	776-20-3-9202-0005	160
COVID-19 NTTHD/MSD addtl Staff (30) thru 8/31	4/23/2020	776-20-3-9202-0016	160
COVID-19 SMS Gateway Services	4/20/2020	776-20-3-9202-0004	160
COVID-19 Remediation Optional Tasks	4/24/2020	776-20-3-9202-0026	160
COVID-19 Digicert Addtl SSL Certificates	4/16/2020	776-20-3-9202-0123	160
COVID-19 Adobe Connect 2000 Addtl seminar roor	4/14/2020	776-20-3-9202-0006	160
COVID-19 TCT OPTIONAL TASKS-CONTRACT # 203	5/22/2020	776-20-3-9202-0174	160
COVID-19-iPad Pro Distribution @ MSD Help Desk	6/16/2020	776-20-3-9202-0173	160
COVID-19 MOU-VC-CORE	6/18/2020	TDA to Bedford MA	160
COVID-19 ATO (Somnoware, AIP, CHAT)	6/20/2020	776-20-3-9202-0277	160
COVID-19 PATIENT HOMELESS PRG IPHONES	6/26/2020	776-20-3-9202-0069	160
COVID-19 Patient iPads (DALC)	6/29/2020	776-20-4-9202-0330	160
COVID-19 PIPS	7/8/2020	776-20-4-9202-0381	160
COVID-19 CHISS Optional Tasks (# 224)	7/8/2020	776-20-4-9202-0383	160

Name of Contract	Date of Transaction	Transaction #	Cost of Contract
COVID-19 Homeless PgmThermometers	TBD	TBD	See comment
COVID-19 VA Health Chat	as of 7/15/20 budget call: back on live		2,128,367.00

NOT APPROVED			
COVID-19 Cirrus VA Clinical Health CHAT	TBD	TBD	4,014,975.00
COVID-19 VA Health Chat	TBD	TBD	2,128,367.00

PO #	Cost of Contract	COVID/CFO Funded	ORH Funded	OCC Funded	Total
E00007	1,298,359.50	1,298,359.50	-	-	1,298,359.50
E00008	5,999,608.38	1,967,793.00	4,031,815	0.38	5,999,608.38
E00009	64,020.00	64,020.00			64,020.00
NONE	20,851	20,851.00			20,851.00
E05007	268,681.83	268,681.83			268,681.83
E00010	7,999,984.14	7,999,984.14			7,999,984.14
E00013	7,399,962.45	-	7,399,962		7,399,962.45
E05009	546,012.03	546,012.00			546,012.00
E00015	12,201,554.25	12,201,554.25			12,201,554.25
E00016	3,212,060.40	3,212,060.40			3,212,060.40
E00017	804,000.00	804,000			804,000.00
E05011	2,383,836.74	2,383,837			2,383,836.74
E05013	77,184.00	77,184.00			77,184.00
E05015	5,834,499.32	5,834,499.32			5,834,499.32
E00019	75,123.75	80,902.50			80,902.50
E05012	52,999.78	52,972.00			52,972.00
E05018	538,985.44	2,156,000			2,156,000.00
E05022	351,750.00	369,690.00			369,690.00
TDA	800,000.00	800,000.00			800,000.00
E05021	500,000.00	500,000.00			500,000.00
E00024	8,065,687.80	8,065,868.00			8,065,868.00
E00025	7,636,967.87	7,636,970.00			7,636,970.00
	633,498.06	633,500.00			633,500.00
	894,418.32	895,000.00			895,000.00
	67,660,045.06	**57,869,738.68**	**11,431,777.45**	**0.38**	**69,301,516.51**

Waiting on justification from COR before submitting to Action group
Submitted to Action Group: 6/24/20 **RACHEL DENIED** 7/6/20

Leadership pulled this request.
Submitted to Action Group: 6/24/20 **RACHEL DENIED** 7/6/20

Check/Balance	
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-	Approved by Rachel: 4/17/20
-	Approved by Rachel: 4/17/20
-	Approved by Rachel: 4/17/20
-	Approved by Rachel: 4/20/20
	Approved by Rachel: 5/7/20
	Approved by Rachel: 5/7/20
	Approved by Rachel: 5/12/20
(27.78)	Approved by Chuck Hume: 4/20/20
1,617,014.56	Approved by Rachel: 5/19/20
17,940.00	Approved by Rachel: 6/14/20
-	Approved by Rachel: 6/9/20
-	Approved by Rachel: 6/20/20
180.20	Approved by RACHEL 6/29/20
2.13	Approved by RACHEL 6/29/20
1.94	Approved by RACHEL 7/7/20
581.68	Approved by RACHEL 7/7/20
21,677.70	

CARES Act
VHA Spend Plan

VHA Summary Level Plan	Submission	Received		FY 2020	FY 2021	Total		Obligated through EOM June	Percent of FY 2020 Plan
Care Delivery Costs (includes community care)	**$15,069,372,310**	**$16,882,272,310**		**$4,664,000,000**	**$9,675,000,000**	**$14,339,000,000**		**$1,883,966,381**	**40.4%**
Hospital Costs	$9,988,500,630	$11,490,923,430		$3,481,000,000	$5,209,000,000	$8,690,000,000		$1,594,539,149	45.8%
Personal Services (Salaries & Awards)								$432,562,067	
Travel & Transportation								$6,084,614	
Contracts including Rents, Communications & Utilities								$171,995,462	
Phamaceuticals								$166,878,675	
Supplies and Materials (including test kits)								$432,676,011	
Equipment								$373,612,489	
Land & Structures including NRM								$10,729,833	
PPE	$3,030,871,680	$3,030,871,680		$500,000,000	$2,200,000,000	$2,700,000,000		$55,720,198	11.1%
Emergency / Urgent Care	$2,050,000,000	$2,100,000,000		$323,000,000	$1,777,000,000	$2,100,000,000		$29,815,451	9.2%
Homelessness				$360,000,000	$489,000,000	$849,000,000		$203,891,583	56.6%
Emergency Management Activities	**$100,560,000**	**$100,660,000**		**$126,000,000**	**$552,000,000**	**$678,000,000**		**$9,787,454**	**7.8%**
Emergency Management Coordination	$16,560,000	$16,560,000		$100,000,000	$500,000,000	$600,000,000		$5,561,803	5.6%
Public Affairs	$9,150,000	$9,150,000		$1,000,000	$2,000,000	$3,000,000		$87,660	8.8%
Physical Security	$74,850,000	$74,850,000		$25,000,000	$50,000,000	$75,000,000		$4,137,991	16.6%
Expanded Telehealth Capacity	**$255,067,690**	**$255,067,690**		**$290,000,000**	**$10,000,000**	**$300,000,000**		**$40,919,093**	**14.1%**
Grants for Construction of State Extended Care Facilities	**$0**	**$150,000,000**		**$0**	**$150,000,000**	**$150,000,000**		**$0**	**0.0%**
TOTAL	$15,425,000,000	$17,388,000,000		$5,080,000,000	$10,387,000,000	$15,467,000,000		$1,934,672,928	38.1%
Transfers pending from base funding								$238,896,338	
				$5,080,000,000				**$2,173,569,266**	**42.8%**

Future Unidentified Costs **$1,921,000,000**

Acceleration of DMLSS to improve ordering and tracking of supplies
Regional Readiness Centers pre-place supplies to level set supply needs for normal operations and emergent situations
Vaccines for Veterans and VHA staff

Anticipated Transfer Requests

Veterans Canteen Service Support
Level setting appropriations based on actual and anticipated expenditures

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAY 2 2 2020

The Honorable William M. "Mac" Thornberry
Ranking Member
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Representative Thornberry:

The enclosed report is in response to the House Report 116-120, page 159, to accompany H.R. 2500, the National Defense Authorization Act (NDAA) for Fiscal Year 2020, which requests the Department to provide a report on Co-Location of Department of Defense (DoD) and Department of Veterans Affairs (VA) Medical Facilities.

As of September 30, 2019, the DoD and VA had 130 sharing agreements with 472 shared services across 148 facilities. Both Departments are working together on Joint Market Assessments to determine health care requirements and identify markets that could benefit from a joint planning, design, leasing, and construction process. However, without a change to title 10, DoD and VA lack the authority to conduct joint planning. DoD has submitted a proposal to change the code during the previous three legislative change cycles, but Congress has not included the proposal in the NDAA. This proposal would give DoD and VA the authority to conduct joint planning, design, leasing and construction.

Thank you for your continued support of the health and well-being of our Service members, veterans, and their families.

Sincerely,

Matthew P. Donovan

Enclosure:
As stated

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAY 2 2 2020

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Thank you for your continued support of the health and well-being of our Service members, veterans, and their families.

Sincerely,

Matthew P. Donovan

Enclosure:
As stated

Report to the Committee on Armed Services of the House of Representatives

Co-Location of Department of Defense and Department of Veterans Affairs Medical Facilities

Requested by: House Report 116-120, Page 159, to Accompany H.R. 2500, the National Defense Authorization Act for Fiscal Year 2020

Office of the Secretary of Defense

The estimated cost of this report or study for the Department of Defense (DoD) is approximately $11,000.00 in Fiscal Year 2019- 2020. This includes $10 in expenses and $11,000.00 in DoD labor.
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Contents

1. PURPOSE

This report is in response to House Report 116-120, page 159, to accompany H.R. 2500, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020, which requests the Secretary of Defense (SECDEF) to provide a report to the Armed Services Committees on the "Co-Location of Department of Defense and Department of Veterans Affairs Medical Facilities."

Specifically, the committee requests the SECDEF to submit a report to the House Armed Services Committee by February 1, 2020, on the following:

(1) a list of facilities where co-location may be possible;
(2) a cost-benefit analysis that highlights efficiencies that could be gained by shared services, personal services contracts, equipment, and other resources; and
(3) a list of facilities that could benefit from a joint planning, design, and construction process for DoD and VA medical facilities.

2. BACKGROUND

The Department of Defense (DoD) and Department of Veterans Affairs (VA) are constantly seeking opportunities for greater sharing of medical resources to include facility space. The DoD/VA Collaboration Office (DVCO) provides a central point of contact within DoD for the White House, Congress, the VA, and other Federal agencies and stakeholders regarding Service member and veteran programs. The DVCO serves as DoD's Executive Secretariat for the Joint Executive Committee (JEC), co-chaired by the Deputy Secretary of Veterans Affairs and the Under Secretary of Defense for Personnel and Readiness. Reporting directly to the JEC is the Health Executive Committee (HEC), co-chaired by the Executive in Charge Veterans Health Administration (VHA) and the Assistant Secretary of Defense for Health Affairs (HA). The HEC priorities range from military medical provider readiness to virtual health to joint sharing of facilities and services. Through the HEC, both Departments are working together on Joint Market Assessments to determine health care requirements. While many facilities have been identified that could benefit from expanded collaboration in these areas, VA and DoD are unable to take action without legislative changes.

For several years, DoD and VA have pursued legislative changes to provide the needed authority to expand their existing collaborative relationship to permit proactive, more detailed joint capital investment planning, construction, and leasing of co-located and shared medical facilities. The Capital Asset Planning Committee (CAPC) has led this effort, advocating to the JEC and Department leadership for this authority. The CAPC is co-chaired by VA's Executive Director, Office of Asset Enterprise Management and DoD's Deputy Assistant Secretary of Defense for Health Resources Management and Policy.

The VA/DoD Medical Sharing Office (MSO), VHA and the DoD/VA Program Office (DVPO), HA facilitate mutually supportive relationships on all matters related to joint health care initiatives between VHA and the DoD. Both offices serve as the primary liaison for their

respective departments' VHA/DoD joint sharing initiatives. The MSO and DVPO provide senior-level leadership and direction for the support and accomplishment of all health care related VHA/DoD Joint Strategic Plan goals, objectives, and performance measures through the use of medical resource sharing agreements. Sharing agreements provide a written structure to exchange clinical and non-clinical resources between VA and DoD medical facilities. In addition, agreements increase patient access to medical services, enhance military medical provider readiness, promote improved efficiency by reducing duplication of services, and encourage the sharing of medical facility space.

This report has been drafted in coordination with DoD's section 703(d) of the NDAA for FY 2017 military medical treatment facility (MTF) right-sizing report.

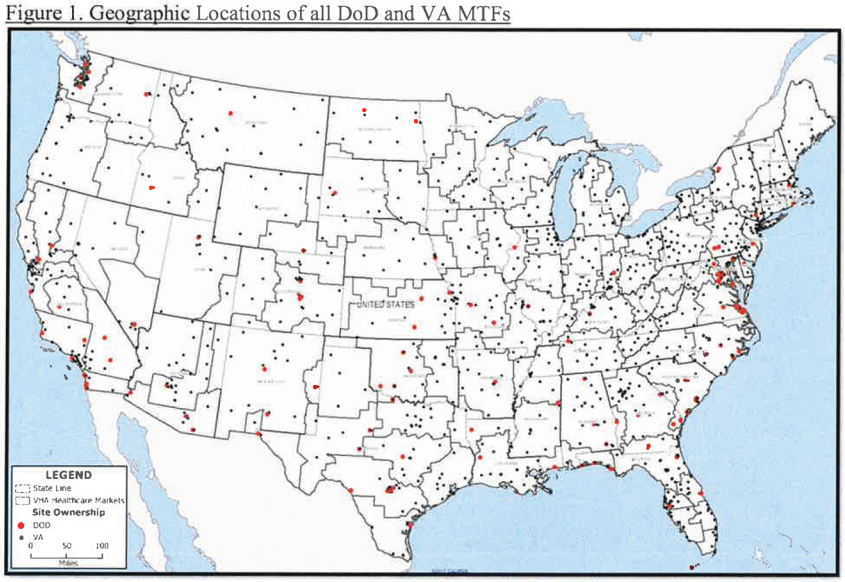
3. POSSIBLE CO-LOCATION FACILITIES

Current Co-Location and Sharing

The DoD and VA have one fully integrated facility (Captain James A Lovell Federal Health Care Center (FHCC) in Chicago) and 34 sites that are co-located or sharing real property locations (See Appendix). As of September 30, 2019, the DoD and VA have 130 sharing agreements with 472 shared services across 148 facilities (61 VA and 87 DoD). In FY 2018, DoD-VA sharing resulted in interagency billing of $195M. This includes $117M in DoD billing VA, $49M in VA billing DoD, and $29M in VA billing TRICARE.

Future Co-Location Possibilities

Figure 1. Geographic Locations of all DoD and VA MTFs



Future co-location opportunities are widespread and numerous due to the considerable proximity of DoD and VA facilities. Geo-mapping of all DoD and VA facilities, regardless of capability, shows an additional 544 co-location possibilities based on a 60-minute drive time.

It is important to note that both DoD and VA have consistently reported that the FHCC, established in 2010, does not yet represent a model that is exportable to other DoD/VA sites. According to an August 2018 letter from DoD and VA leadership to the Honorable Richard Durbin, the FHCC demonstration project was expected to improve access and quality of care, while also achieving cost savings in common functional areas. The Departments' July 2016 joint Report to Congress (RTC) about the FHCC outlined the inherent challenges associated with the FHCC model to include the lack of a common Electronic Health Record (EHR). The RTC also included recommendations to bring FHCC closer to achieving its original goals of improved access, quality, and cost effectiveness. Both DoD and VA are pursuing these recommendations, to include a common EHR, but the desired outcomes, especially in the area of cost effectiveness, had not been achieved in 2018.

Determining Co-Location Feasibility

The VA is currently collaborating with the DoD Market Visioning Studies (Strategic Market Assessments) to complete the VA Market Assessments as outlined by section 106(a) of the VA MISSION Act of 2018. The market assessments provide opportunities for creating high performing health care networks by evaluating market demographics, estimating demand/supply, and assessing quality, satisfaction, accessibility, cost, facility condition, and mission impact. Where there is a DoD presence in the VHA Health Care Market, DoD is participating in preliminary analyses, site visits, and market assessment interviews. DoD is also providing capacity data to fulfill the requirements outlined in section 106(a)(1)(D) of the VA MISSION Act of 2018, which states, "Each Market Area Assessment. . . shall include the following. . . (D) an assessment obtained from other Federal direct delivery systems of their capacity to provide health care to Veterans." The outcomes from each of the market assessments will drive market optimization and capital plans that align with the regional Veterans Integrated Service Network (VISN) and National DoD-VA Strategic Plans. The 96 VHA Market Assessments are scheduled for completion in the Fall of 2020, and will then be reviewed by DoD and VA leadership. Subsequently, opportunities that meet the recommendation criteria established by the VA Secretary of Veterans Affairs (section 203 of the VA MISSION Act of 2018; due: May 2021) will be delivered to the VA and Asset Infrastructure Review Commission for consideration.

Feasibility of co-location sites for DoD is largely dependent upon identifying those DoD sites that have latent facility and provider capacity to support co-location and patient care sharing, respectively. Latent facility space capacity creates opportunities for the VA to operate within MTFs. Where latent provider capacity exists, based on established Defense Health Agency (DHA) provider productivity standards, DoD treating VA patients may be more cost-effective for the Departments, while also providing opportunities to maintain wartime medical skills. As the DHA gains administrative direction and control of the MTFs, DoD is placing greater emphasis on optimizing capacity within the direct care (military) system. The DoD and VA are already partnering to meet the following JEC priority: "VA and DoD will establish a process to increase VA purchased care patient referrals to military medical treatment facilities with excess capacity to support Graduate Medical Education (GME) and wartime skills maintenance."

4. EXAMPLES OF EFFICIENCIES GAINED

Cost-benefit analyses highlight efficiencies that could be gained by shared services, personal services contracts, equipment, and other resources as the following examples demonstrate:

Walter Reed National Military Medical Center's (WRNMMC) Neurosurgery Service

DoD-VA collaboration supplements both GME programs and wartime skills maintenance by offering VA beneficiaries treatment in a DoD facility. For example, during FY 2019, WRNMMC Neurosurgery Service completed 438 inpatient and outpatient referrals for VA patients. Because of this additional high acuity VA workload, the neurosurgery residency has added one additional resident slot for the upcoming year. In addition, the partnership in FY 2019

resulted in $4.5M of care billed to the VA at the standard 20 percent discounted rate. Despite enterprise-wide VA-DoD reimbursement challenges, the Neurosurgery Service experienced a 96 percent collection rate. The DoD and VA continue to pilot a standard reimbursement process, which upon completion and validation is expected to be implemented enterprise-wide.

Naval Hospital Beaufort (NHB) and Ralph H. Johnson Veterans Affairs Medical Center (RHJVAMC)

A Joint Incentive Funds (JIF) Project between NHB and RHJVAMC established a dermatology service for DoD and VA beneficiaries to be delivered at the NHB, Beaufort SC. Neither clinic alone could justify establishing a dermatology clinic, but the combined demand for care was great enough to pursue a JIF Project. The joint clinic met the combined demand for VA and DoD dermatology, speeding access to care and reducing travel time for both VA and DoD beneficiaries. The Joint Dermatology Clinic avoided $280K in annual network costs while realizing a 12.5 percent return on investment.

VA Northern California Health Care System (VANCHCS) and David Grant USAF Medical Center (DGMC)

As part of a DoD-VA Health Care Resources Sharing Program between the VANCHCS and DGMC, the VA employs 133 full time staff within DGMC. Veterans utilize the emergency department; inpatient care; outpatient care; radiation therapy; dialysis; inpatient mental health; heart, lung, vascular care (HLV); hematology oncology; orthopedics; and specified diagnostic services. In FY 2019 veterans accounted for over 19,000 outpatient visits, 1,800 admissions, and 51.75 percent of surgical cases for FY 2019 including 395 HLV, 263 orthopedic, and 262 neurosurgery cases.

March Air Reserve Base, Riverside, California

The VA established 25,000 square feet of administrative space in an unused DoD building, paying DoD $1,895.00 per month or $22,740.00 per year. Comparable office space in nearby Riverside rents for approximately $25.00 per square foot. Therefore, the VA is paying $22,740.00 per year for a space that is estimated to be worth $625,000, saving the VA $602,260.00 per year.

Lawton VA Outpatient Clinic, Fort Sill, Oklahoma

The VA occupies, free of charge, a 34,471 square foot DoD building directly adjacent to the Reynolds Army Health Clinic on Fort Sill. Comparable space in nearby Oklahoma City rents for approximately $20.00 per square foot. Therefore, the VA is paying $0 per year for a space that is estimated to be worth $689,420.00 per year.

5. POSSIBLE JOINT CONSTRUCTION SITES

Current Joint Planning

DoD and VA do not currently have legislative authority to conduct joint planning under title 10, United States Code. DoD submitted a proposal to change the code during FY 2014, FY 2019, and FY 2020. VA submitted companion legislation to change the authority for joint planning under title 38 beginning in FY 2014 through FY 2021. Most recently, the proposal was transmitted to Congress for consideration for inclusion in the NDAA for FY 2021. The Departments are jointly pursuing Combined Legislation to allow this authority under title 10 and title 38 in FY 2021.

Future Joint Planning Possibilities

Geo-mapping shows 578 VA and DoD facilities within 60 minutes of each other that, based on proximity, may benefit from future joint planning. Specifically, aging infrastructure offers multiple opportunities for joint planning. The DoD and VA have identified 10 sites that may benefit from joint planning, design, and construction in the near future.

Installation / Area	Type	DHA and VA Collaboration	Status
Fredericksburg, VA	Project	Ambulatory Care Center Lease	Ongoing
Travis Air Force Base (AFB), CA	Project	Inpatient Modernization (Existing Resource Sharing Agreement)	Ongoing
Colorado Springs, CO	Study	Colorado Springs Market Visioning	Ongoing
San Antonio, TX	Study	San Antonio Market Visioning	Ongoing
El Paso, TX	Coordination	Fort Bliss / El Paso Market Coordination Meetings	Ongoing
Wright-Patterson AFB, OH	Study	Facility Assessment Study	Planned
Eglin AFB & Naval Air Station Pensacola, FL	Study	Florida Panhandle Market Infrastructure Study	Ongoing
San Diego, CA	Study	San Diego Market Infrastructure Study	Planned
Jacksonville, FL	Study	Jacksonville Market Infrastructure Study	Planned
Honolulu, HI	Study	Hawaii Market Infrastructure Study	Planned

Determining Joint Planning Feasibility

Both Departments are working together on Joint Market Assessments to determine health care requirements and identify markets that could benefit from a joint planning, design, and construction process. However, without a change to title 10 and title 38, DoD and VA lack the authority to conduct joint planning and funds transfer for joint construction projects

6. CONCLUSION

As of September 30, 2019, the DoD and VA had 130 sharing agreements with 472 shared services across 148 facilities (61 VA and 87 DoD). In FY 2018, DoD-VA sharing resulted in interagency billing of $195M. There are numerous additional opportunities for DoD-VA co-location. Many DoD-VA sharing projects have proven successful but these projects, in general, continue to be hampered by dual credentialing, information sharing, and reimbursement challenges. Although there are numerous opportunities for large-scale joint planning, design, and construction, DoD and VA lack the statutory authority to conduct joint planning.

VA and DoD continue to seek legislative authority to expand their existing collaborative relationship to permit proactive, more detailed joint capital investment planning, construction, and leasing of shared medical facilities. Enacting the Combined Legislation, currently proposed for FY 2021, will provide inherent authority for both Departments to transfer and accept funds appropriated for the planning and design, major (authorized) and minor construction, and leasing of shared medical facilities. This will eliminate a major obstacle to collaboration on joint capital projects, thereby improving the efficiency, accessibility, and cost-effectiveness of health care delivery for beneficiaries including Service members, veterans, and taxpayers.

Short of a change to title 10 and title 38, Congress could permit DoD and VA to initiate demonstration studies for proposed facility planning at specific sites. These studies would be conducted in parallel with NDAA submissions for the DoD and VA Like Legislation. The studies, using the facilities identified in Section 5, would be structured on collaborative opportunity evaluation criteria to include, but not limited to, DoD-VA location and market selection, DoD-VA beneficiary requirements, DoD readiness, DoD-VA staffing benefits, and DoD-VA cost factors. These studies would determine the basis for expanded DoD-VA sharing, and identify programs and policies to support future collaboration.

7. ACRONYMS

AFB	Air Force Base
BACH	Basset Army Community Hospital
CAPC	Capital Asset Planning Committee
CAVHCS	Central Alabama Veterans Health Care System
CBOC	Community Based Outpatient Clinic
DGMC	David Grant USAF Medical Center
DHA	Defense Health Agency
DoD	Department of Defense
DVCO	DoD/VA Collaboration Office
DVPO	DoD/VA Program Office
EHR	Electronic Health Record
FHCC	Federal Health Care Center
FY	Fiscal Year
GME	Graduate Medical Education
HA	Health Affairs
HCS	Health Care System
HEC	Health Executive Committee
HLV	heart, lung, vascular care
JEC	Joint Executive Committee
JIF	Joint Incentive Fund
MSO	Medical Sharing Office
MTF	military medical treatment facility
NDAA	National Defense Authorization Act
NHB	Naval Hospital Beaufort
RHJVAMC	Ralph H. Johnson Veterans Affairs Medical Center
RTC	Report to Congress
SECDEF	Secretary of Defense
VA	Department of Veterans Affairs
VAGCVHCS	VA Gulf Coast Veterans Health Care System
VAMC	Veterans Affairs Medical Center
VANCHCS	VA Northern California Health Care System
VHA	Veterans Health Affairs
VISN	Veterans Integrated Service Network
WBAMC	William Beaumont Army Medical Center
WRNMMC	Walter Reed National Military Medical Center

APPENDIX: Existing DoD/VA Co-Location Sites

Fully Integrated Facility

VISN 12: North Chicago, IL – Captain James A. Lovell FHCC integrates the North Chicago VA Medical Center and Naval Health Clinic Great Lakes.

Co-Located or Sharing Real Property Locations

VISN 2: Keller Army Community Hospital, West Point, NY occupies space at the VA Hudson Valley in Montrose, NY.

VISN 4: Wilkes-Barre Veterans Affairs Medical Center (VAMC) has a VA clinic at Tobyhanna Army Depot, PA.

VISN 5:

- Martinsburg VAMC has a Community Based Outpatient Clinic (CBOC) adjacent to Barquist Army Health Clinic at Ft. Detrick, MD.
- Washington DC VAMC operates a CBOC within the Ft Belvoir Community Hospital on Ft Belvoir, VA.
- Baltimore VA Health Care System (HCS) operates a CBOC adjacent to Kimbrough Ambulatory Care Center on Ft Meade, MD.

VISN 6: Fayetteville VAMC and Womack Army Medical Center share space in Ft. Bragg Garrison-owned space at the Soldier Support Center, Fayetteville, NC.

VISN 7:

- Naval Health Clinic Charleston (Goose Creek) and a Ralph Johnson VAMC CBOC were jointly constructed on Joint Base Charleston at Goose Creek, SC.
- NHB has the Ralph Johnson VAMC CBOC located in NHB.
- Carl Vinson VAMC (Albany CBOC) shares clinical space with the Navy on Albany Marine Corps Logistics base in Albany, GA.
- Central Alabama Veterans Health Care System (CAVHCS) has a primary care clinic at Lyster Army Health Clinic, Ft. Rucker, AL.
- CAVHCS has a VA podiatry clinic at Maxwell AFB, AL.
- CAVHCS occupies modular clinical space on Ft. Benning.

VISN 8: Naval Branch Health Clinic Key West, Naval Hospital Jacksonville and Key West CBOC, Miami VA HCS jointly constructed clinics on their respective naval bases.

VISN 9:

- Louisville, KY, VAMC has a CBOC at Ireland Army Health Clinic, Ft. Knox, KY.
- Nashville VAMC has a CBOC at Arnold AFB, TN.

VISN 15: St. Louis VA HCS operates a Compensation and Pension clinic in the 375th Medical Group clinic on Scott AFB.

VISN 16:

- VA Gulf Coast Veterans Health Care System (VAGCVHCS) and Keesler Medical Center, 81st Medical Group, have a Center of Excellence Model of Sharing to include: Joint Cardiovascular Care Centers and Joint Business Office Center.
- VAGCVHCS and Naval Health Clinic Pensacola operate a Joint Ambulatory Care Clinic on DoD property outside the gates of the Naval Hospital Pensacola.
- VAGCVHCS has a CBOC co-located with Navy outside the gates of Naval Support Activity, Panama City, FL.
- VAGCVHCS has a CBOC on DoD property outside the gates of Eglin AFB's, 96th Medical Group, Eglin AFB, FL.

VISN 17:

- Audie Murphy VAMC and Wilford Hall Ambulatory Surgical Center (AF) occupy VA commercially leased space for a clinic (originally funded by the VA-DoD JIF) San Antonio, TX.
- El Paso VA HCS and William Beaumont Army Medical Center (WBAMC), Ft. Bliss share an outpatient clinic and ambulatory surgery service co-located with the WBAMC.

VISN 19:

- Oklahoma City VAMC occupies space for a CBOC at Ft. Sill, OK.
- Oklahoma City VAMC occupies space for a CBOC at Wichita Falls, on Sheppard AFB.
- Denver, CO, VAMC's new hospital includes space for a Buckley AFB clinic.

VISN 20:

- Alaska VA HCS built a Health Care Center on 673rd Medical Group, Elmendorf AFB land outside the gates of the AFB, which connects to the AF hospital via a corridor. Alaska VA HCS also shares clinic space with 673rd Medical Group.
- Alaska VA HCS operates its Fairbanks, AK, CBOC within Basset Army Community Hospital (BACH), Ft. Wainwright, AK, with ancillary services provided by BACH specialty care and inpatient services provided on a space available basis.

VISN 21:

- VANCHCS (Fairfield CBOC) operates an outpatient clinic on Travis AFB and shares clinic space with David Grant Air Force Medical Center, 60th Medical Group.
- VANCHCS shares space at its McClellan Outpatient Clinic, Sacramento, CA, with David Grant Medical Center (AF) for an Air Force clinic.
- Palo Alto VA HCS recently open the new co-located VA Gourley CBOC with Army CALMED in Marina, CA.
- VA Pacific Islands HCS has a Medical Center located adjacent to Tripler Army Medical Center.
- VA Guam CBOC shares space on Navy land outside the gate of Naval Hospital Guam.

VISN 22:

- Loma Linda VA HCS and March Air Reserve Air Base co-located administration building on March Air Base.
- 377th Medical Group Clinic, Kirtland AFB operates a clinic on New Mexico VA HCS property.