

**Official Responses to Questions for the Record
in connection with
The Senate Committee on Finance’s Consideration of the Nomination of Christi A. Grimm to be
Inspector General, Department of Health and Human Services**

Chairman Ron Wyden

- 1) Please outline your commitment regarding the work HHS OIG plans to take on with respect to health parity laws (which say mental health should be treated like physical health) and particularly how you would investigate the types of dodges we’re seeing today by companies, insurers and other entities, that essentially get around the commitment to parity.**

The Department of Health and Human Services, Office of Inspector General (HHS-OIG) is committed to continuing and expanding our oversight of equitable access to behavioral health services in HHS programs, including issues related to mental health parity requirements. This critically important topic would continue to be a priority if I am confirmed. Appendix 1 describing reports recently issued and currently underway related to behavioral health is attached.

With respect to the specific issue of health parity laws, HHS-OIG is developing work assessing Medicaid managed care organization (MCO) compliance with applicable provisions of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). MHPAEA parity requirements apply to coverage offered by Medicaid MCOs.¹ This work is still being planned and specific elements may change as the proposal is finalized. Potential areas of focus under consideration for this audit include potential barriers created by the MCOs, such as placing limits on mental health service utilization; other MCO actions that may create financial barriers to beneficiaries accessing mental health services, such as applying increased copayments and deductibles; and how state Medicaid agencies ensure that MCOs comply with applicable parity laws and related MCO contract requirements. HHS-OIG would be pleased to provide a scope and methodology briefing once an audit proposal is completed and approved.

Focusing on compliance with MHPAEA through the lens of Medicaid managed care provides us with our strongest opportunity to produce high-impact work regarding MHPAEA compliance, given our jurisdiction and data available to us. Medicaid managed care currently covers over 80 percent of all Medicaid beneficiaries, and Medicaid is the largest payor for mental health services.

We anticipate that findings and recommendations related to Medicaid MCOs would be valuable to policymakers considering a range of parity issues across various plans that provide coverage to approximately 65 million individuals.

Our oversight plan with respect to MHPAEA compliance is to start with Medicaid MCOs, as described above, and to continue to research other potential options for oversight on this important issue. In addition to Medicaid MCOs, MHPAEA and related laws apply to a broad range of health insurance plan

¹ The Social Security Act applies the MHPAEA parity requirements to coverage offered by Medicaid MCOs, Medicaid benchmark and benchmark-equivalent plans (referred to as Medicaid Alternative Benefit Plans), and the Children’s Health Insurance Program (§§ 1932(b)(8), 1937(b)(6), and 2103(c)(7) & (f)(2) of the Social Security Act, respectively).

types, including employer-sponsored plans, group health plans, and individual market plans. In most instances, HHS-OIG does not have the authority to oversee plan compliance with the MHPAEA and related laws because HHS does not regulate or fund most health plans subject to MHPAEA. HHS-OIG is authorized to conduct, supervise, and coordinate audits and investigations relating to HHS programs and operations. For issuers and health plans that do not receive HHS funding and do not constitute HHS programs or operations, HHS-OIG does not have jurisdiction to examine those issuers or health plans. HHS-OIG would be happy to provide a briefing and would appreciate an opportunity to assess how the Committee's interests in mental health parity issues align with potential work that falls under HHS-OIG's authorities.

More broadly, HHS-OIG is committed to examining issues of access, equity, and parity of behavioral health services, beyond the specific application of MHPAEA. In addition to ongoing work described in the Appendix 1, future work could include looking at parity through Medicare data, for example. The Medicare Payment Advisory Commission issued a report describing concerns that some Medicare Advantage plans may discriminate against beneficiaries who require mental health services by requiring cost-sharing amounts substantially higher than Medicare fee-for-service levels. This is an area of potential interest as HHS-OIG considers future work. HHS-OIG is also exploring new work to examine the use of prior authorization and other administrative steps by Medicare Advantage organizations and Medicaid managed care organizations that may result in burdens or delays for beneficiaries to access behavioral health services.

Based on our previous communication with the Senate Committee on Finance staff, HHS-OIG has been developing new work to evaluate the availability of behavioral health care providers in traditional Medicare, Medicare Advantage, and Medicaid managed care. This work may assess and compare across these programs the extent to which behavioral health providers, including those listed in managed care plans' networks, are serving enrollees and able to offer appointments to new patients.

Should I be confirmed, I look forward to engaging with you and your staff as we further develop and prioritize these and other ideas for new work to address required parity and equitable beneficiary access to mental and behavioral health care.

2) Please detail how the HHS OIG would take on work (and review the work done to date) that would ensure access to telehealth services while not creating a path to fraud.

HHS-OIG has a comprehensive telehealth oversight and enforcement strategy. It is important that new telehealth policies and technologies with potential to improve care and enhance access achieve these goals and are not compromised by fraud, abuse, or misuse. To accomplish that, OIG's telehealth strategy involves:

- conducting significant oversight work to ensure that services are paid appropriately, to better understand potential telehealth challenges and opportunities, and to further target high-risk areas with subsequent work;
- monitoring telehealth claims continually for aberrant trends, outliers, and potential improper payments;
- taking law enforcement action, as appropriate, against bad actors who exploit telehealth technology and conduct sham remote visits to bill fraudulently for other items and services; and
- informing congressional and HHS stakeholders of the results of our work and of

recommendations for program improvements to promote access and safeguard against fraud, abuse, or misuse.

Telehealth Oversight

HHS-OIG recently announced seven work plan items and issued three reports addressing the telehealth used to provide behavioral health services in Medicaid. These recent work plan items and reports are described in the attached Appendix 2.

HHS-OIG's telehealth oversight will provide objective findings and recommendations to further inform policymakers and other stakeholders as they consider changing telehealth beyond the public health emergency. For example, we are:

- 1) assessing potential program integrity risks associated with expanded telehealth services authorized by the public health emergency,
- 2) assessing important telehealth utilization and access issues, such as how the use of telehealth during the pandemic compares to the use of the same services delivered in-person, and
- 3) making an early assessment of whether services such as evaluation and management and psychotherapy comply with Medicare requirements.

Many of these telehealth oversight reports are expected to be completed in calendar year (CY) 2022. As appropriate, HHS-OIG's telehealth oversight will recommend suitable safeguards to help ensure that telehealth operates effectively and efficiently to enhance access; deliver quality health care; improve health outcomes; and mitigate potential fraud, abuse, and misuse.

As HHS-OIG's oversight informs how and the extent to which the public health emergency affected the delivery of telehealth services, HHS-OIG will assess any associated risks. HHS-OIG continuously plans for new work using a risk-based approach. As such, the results of ongoing telehealth work will inform planning for future additional work targeted to high-risk areas.

We are coordinating with other Offices of Inspector General as part of the Pandemic Response Accountability Committee to plan work related to telehealth issues that affect multiple Federal agencies. Although work planning is still ongoing, HHS-OIG expects this work will provide valuable insights into telehealth service delivery and payment across several Federal agencies. These insights may further inform policymakers and other stakeholders about the successes and challenges that span Federal programs.

Monitoring Telehealth Claims

HHS-OIG's direct access to Medicare data allows for sophisticated monitoring of telehealth claim utilization patterns. By identifying outliers and other patterns, HHS-OIG generates potential leads for investigations or spots potential program integrity risks that would benefit from further oversight. We have been monitoring these data since the beginning of the pandemic in spring 2020 via automated reports that are shared with the Centers for Medicare & Medicaid Services (CMS) and our law enforcement partners. HHS-OIG will continue this effort and improve our data analytics by incorporating field intelligence from our law enforcement agents, auditors, and evaluators.

Law Enforcement Actions Addressing Telefraud and Telehealth Fraud

HHS-OIG is committed to taking swift action against bad actors who seek to exploit telehealth and remote care. To date, most of our enforcement has involved telefraud schemes that use phone calls or sham remote visits to engage with a beneficiary to order or prescribe medically unnecessary testing, equipment, or prescriptions.

These telefraud scams target Medicare beneficiaries through aggressive telemarketing techniques to confuse and take advantage of the growing acceptance of remote care. The amount of alleged fraud associated with these schemes is in the billions of dollars and is largely associated with fraud related to medically unnecessary claims for durable medical equipment (DME), various types of laboratory tests, and pain medication.

To protect beneficiaries and recover billions in alleged fraud, HHS-OIG, the Department of Justice (DOJ) and our law enforcement partners have conducted four large-scale takedowns that have targeted telefraud schemes: [Operation Brace Yourself](#), the [2020 National Health Care Fraud Takedown](#), the [2021 COVID-19 Takedown](#), and the [2021 National Health Care Fraud Enforcement Action](#).

Although the schemes charged in these takedowns are not identical, most leverage phone calls or sham remote visits to expand the reach of the fraud to Medicare beneficiaries no matter where the criminals might be. Perpetrators “cold call” Medicare beneficiaries to connect them with co-conspirator health care providers who conduct sham remote visits. The health care provider then orders unnecessary DME, testing, or prescriptions. In some cases, the health care provider signs fraudulent orders from their desk without even attempting to talk with the beneficiaries. The criminal organizations sell those fraudulent orders to DME companies, laboratories, or pharmacies, who then bill Medicare fraudulently.

HHS-OIG continues to work with our law enforcement partners and the CMS to prevent and take action against the bad actors perpetrating telefraud schemes. For example, CMS revoked the billing privileges of 256 medical professionals for their involvement in telefraud schemes in the 2020 National Takedown. We have published materials on our website and social media and have partnered with government and private stakeholders to make Medicare beneficiaries aware of these telefraud scams so they can take steps to protect themselves.

In most telefraud cases to date, the criminals are not engaging in telehealth fraud. The main target for these schemes is medically unnecessary ordering of DME and laboratory tests, and prescriptions.

HHS-OIG is aware of allegations of telehealth fraud by health care facilities and providers—the billing for a telehealth service that does not occur or upcoding of telehealth claims. Although such allegations make up a small portion of our enforcement work as of September 2021, HHS-OIG is monitoring for indicators of increases in fraudulent billing for telehealth services. In the instances where this has occurred already, HHS-OIG and DOJ have taken action against those health care providers.

As we continue to learn from our significant body of telehealth oversight and enforcement work, HHS-

OIG will continually assess the need for additional compliance materials to help those providers who want to comply with laws and provide high-quality telehealth services to their patients.

Informing Stakeholders

In instances where HHS-OIG finds significant risks that are supported by data and our analysis, audits, evaluations, and investigations, HHS-OIG is committed to keeping this Committee, Congress, and other stakeholders informed. HHS-OIG recognizes the importance of providing timely, independent, and objective information as policymakers consider telehealth expansion or other changes beyond the public health emergency. We have already provided technical assistance to Congress, including the Senate Committee on Finance, earlier this year that highlight potential risks based on high-level, early data analyses.

Should I be confirmed, I look forward to continued engagement with the Senate Committee on Finance on HHS-OIG's telehealth oversight and enforcement work.

- 3) Over the last 19 months, Congress has passed several COVID-19 relief bills containing more than \$175 billion in financial relief for health care providers. Providers have faced enormous challenges in responding to this pandemic, including lower revenues and higher costs. This support has been essential to their ability to continue serving their communities. Oversight of these funds will be critical to ensuring these funds are utilized for their intended purpose, and to understand the impact of the pandemic on providers. I understand HHS OIG is currently conducting an audit of the Provider Relief Funds.**

If confirmed, what will be your focus in conducting oversight of these funds?

If confirmed, I will continue to focus on ensuring that the Department's distribution of Provider Relief Fund (PRF) payments are accurate and funds were used as intended and not wasted. PRF payments were distributed quickly to address an emergency, and some controls may not have been in place. These circumstances increase the risk of improper payments, including payments being calculated incorrectly, being unsupported by reasonable and appropriate documentation, or being paid to ineligible providers.

HHS-OIG has ongoing work looking at PRF payments. We are conducting a series of audits on the PRF general and targeted distributions in three stages. The first two audits focus on HHS and Health Resources and Services Administration (HRSA) controls, and the third focuses on provider compliance. HRSA is the HHS agency administering the PRF. First, HHS-OIG is assessing the effectiveness of HHS and HRSA's controls over the accuracy of payments, ensuring payments met Federal requirements and grant terms, and provider eligibility of funds received for the automatic distributions. Second, we are assessing HHS and HRSA's controls over the accuracy of payments, provider eligibility of funds received, and other PRF program requirements (e.g., provider documentation) for the application-based and other general distributions. Third, we are conducting a series of audits of providers' compliance with PRF reporting and expenditure requirements to determine whether claims for services complied with Federal requirements.

Through this ongoing oversight work, HHS-OIG expects to make recommendations to improve HHS and HHS program oversight of any ongoing emergency spending and future emergency spending. Potential improvements may include more effective communications and internal controls among entities involved in determining, allocating, and distributing the funding, as well as recommendations to recover any

identified overpayments. Additionally, HHS-OIG is conducting an evaluation of the geographic distribution of provider relief funds to communities disproportionately impacted by adverse COVID-19 outcomes. Looking forward, HHS-OIG is exploring a potential evaluation of PRF payments to nursing homes.

HHS-OIG is continuing to coordinate on oversight of cross-cutting issues related to pandemic funds with the Pandemic Response Accountability Committee (PRAC), which promotes transparency and ensures coordinated, comprehensive oversight of the Government's spending and COVID-19 response to prevent and detect fraud, waste, and abuse, and mismanagement.

HHS-OIG would be happy to provide a briefing for you and your staff on this issue.

- 4) Today, over 25 million Medicare beneficiaries enroll in private health plans in order to access their Medicare benefits, as well as supplemental benefits, such as post-hospital meals delivered to their homes and lower cost-sharing for doctor visits.**

By 2025, the Congressional Budget Office expects half of all Medicare beneficiaries will enroll in a Medicare Advantage plan. Last year, Medicare spent \$320 billion in payments to private plans, which is about 40% of all Medicare spending. In testimony before the House, the Government Accountability Office reported that the improper payment rate within the Medicare Advantage program is 10 percent. If correct, that means in 2020, \$32 billion in Medicare payments in Medicare Advantage should not have been made. Oversight of this program will be critical to ensure Medicare beneficiaries receive benefits they are entitled to and longevity of the program remains for all Medicare recipients.

Can you tell us why Medicare Advantage's improper payment rate is so high? What can Congress do to reduce these improper payments?

With respect to the Medicare Advantage, the Centers for Medicare & Medicaid Services (CMS) is responsible for calculating the Medicare Part C/Medicare Advantage gross improper payment estimate. In the Department's [Fiscal Year \(FY\) 2020 Agency Financial Report](#), CMS reported a 6.78-percent error rate or \$16.27 billion. This is a decrease from the prior year's estimate of 7.87 percent.

As context, the methodology that CMS uses for the Medicare Part C error rate estimates improper payments resulting from errors in beneficiary risk scores used in risk adjustment. The primary component of most beneficiary risk scores is clinical diagnoses submitted by the plan. If medical records do not support the diagnoses submitted to HHS, the risk scores may be inaccurate and result in payment errors. The Part C improper payment estimate is based on medical record reviews conducted under HHS's annual Part C Improper Payment Measurement process, through which HHS identifies unsupported diagnoses and calculates corrected risk scores. CMS risk-adjusts payments by paying higher capitated payments to Medicare Advantage companies for beneficiaries expected to have higher-than-average medical costs based on their diagnoses. This practice may create financial incentives for Medicare Advantage companies to make beneficiaries appear as sick as possible.

With respect to one of the causes of improper payments in Medicare Advantage (errors in risk scores used in risk adjustment), findings from HHS-OIG reports raise concerns about the extent to which Medicare Advantage companies may have inappropriately leveraged chart reviews and beneficiary health risk

assessments to maximize risk-adjusted payments. HHS-OIG found that diagnoses that Medicare Advantage companies reported only on chart reviews (a review of beneficiaries' medical records to identify unreported or misreported diagnoses)—and not on any service records in the encounter data—resulted in an estimated \$6.7 billion in added risk-adjustment payments for 2017. HHS-OIG also found that in 2017 Medicare Advantage companies received an estimated \$2.6 billion in risk-adjustment payments from diagnoses reported only on health risk assessments. Although these assessments are intended to promote access to and coordination of needed care, there were no encounter records for any other services for these beneficiaries for these diagnoses. A small number of companies drove most of these risk-adjustment payments deriving solely from chart reviews and health risk assessments. These findings raise a payment integrity concern. If diagnoses from these chart reviews or health risk assessments are inaccurate or unsupported, the associated risk-adjusted payments would be inappropriate.

In addition, HHS-OIG has performed a number of risk-adjustment data validation audits to determine whether diagnosis codes that were submitted by Medicare Advantage companies to receive a higher payment were supported by underlying medical records as required. HHS-OIG used data analytics to help identify particularly high risk diagnosis codes and focused some of our audit work in these high-risk areas. HHS-OIG's audits found that overpayments existed where Medicare Advantage companies submitted diagnosis codes that increased risk scores but were not supported by underlying medical records. As a result, these Medicare Advantage companies should not have received these risk-adjustment payments from CMS. HHS-OIG risk-adjustment data validation audits are a key oversight tool in Medicare Advantage and result in the identification of overpayments that can be returned to the program. HHS-OIG plans to continue to perform audits in this area.

HHS-OIG does not currently have legislative recommendations regarding reducing improper payments in Medicare Advantage; however, we have numerous recommendations to CMS to target and strengthen its oversight of Medicare Advantage companies' use of chart reviews and health risk assessments. We have also recommended that CMS reconsider whether to allow Medicare Advantage companies to use chart reviews that are not linked to service records and in-home health risk assessments as sources of diagnoses for risk adjustment.

Although the Part C improper payment rate has improved over the last couple of years, CMS has not implemented a recovery audit program in Part C, especially for risk-adjustment payments—the primary vulnerability in Part C. HHS-OIG recommends that CMS explore alternative ways to conduct Part C recovery audits.

HHS-OIG briefed your staff in May 2021 about our Medicare Advantage body of work, and we would be happy to provide follow-up briefings for you and your staff.

Senator Maria Cantwell

- 1) Nursing homes and skilled nursing facilities have been particularly hard hit during the COVID-19 pandemic. A nursing facility in Kirkland, Washington has the site of the first U.S. death from the coronavirus, and 39 residents of the facility died within four weeks.**

In a recent report, the HHS Inspector General's Office found that during 2020, two in five Medicare beneficiaries in nursing homes were diagnosed with COVID-19. It is also found

that almost 1,000 more deaths occurred per day in the facilities during April 2020 than during April 2019, increasing the mortality rate by 5 percent.

Long-term care facilities have been entrusted to take care of our seniors and residents should not have to fear for their own safety while having lived in isolation away from friends, family, and visitors during the pandemic. This situation is preventable and unacceptable.

I share your commitment to protecting nursing home residents and appreciate your reference to HHS-OIG's extensive work in this area. The devastating toll that the COVID-19 pandemic has taken on Medicare beneficiaries in nursing homes demonstrates the need for increased action to mitigate the effects of the ongoing pandemic and to avert such tragedies from occurring in the future. Nursing homes should be places of comfort and healing, and we owe our nation's aging population better. If confirmed, I plan to tackle this issue as my top priority, employing an oversight strategy to raise nursing home performance, put residents first, and improve oversight to ensure that problems are detected and remedied quickly. HHS-OIG greatly appreciated the opportunity to testify before the Senate Committee on Finance at a hearing entitled '[Promoting Elder Justice: A Call for Reform](#)' on July 23, 2019, and I look forward to continuing a collaborative dialog with this Committee should I be confirmed.

HHS-OIG has work underway that will build on the report you reference, seeking to better understand nursing home challenges resulting from the COVID-19 pandemic and strategies to combat those challenges. The goal of this body of work is to help protect the health and safety of the vulnerable nursing home population as the pandemic continues, and to use these lessons to improve nursing home safety and quality moving forward.

- a) The American Rescue Plan Act that Congress passed in March included \$250 million for states to deploy nursing home strike teams to assist with cases of COVID-19 among residents and staff. I have heard concerns, including from my home state of Washington, that recipients have had difficulty understanding the requirements to receive HHS program funding. Do states have the necessary resources and clear information to access funding for nursing home strike teams? If not, what do you think are the barriers preventing states from accessing this money?**

HHS-OIG does not currently have work examining American Rescue Plan Act funding to States for deployment of nursing home strike teams. We have work related to other pandemic-related appropriations, such as distributions to healthcare entities through the PRF. HHS-OIG continually conducts work planning to identify areas that warrant our review, and examples of HHS-OIG's extensive nursing home work are provided in the next response. We note your interest in this funding and would like to hear more about these reported difficulties and your related concerns.

- b) The same report that I mentioned also found that about 50 percent of Black, Hispanic, and Asian Medicare beneficiaries in nursing homes contracted COVID-19, compared to 41 percent of white beneficiaries. What is the reason behind this disparity? How do you recommend that we address this issue?**

Thank you for your attention to our work. As you reference, we reported disturbing differences in infection and death rates for nursing home residents, with Black, Hispanic, and Asian Medicare

beneficiaries experiencing higher rates of infection and greater increases in mortality as compared with White beneficiaries. This initial report did not evaluate the causes of these differences, and we did not make recommendations. Follow-up reports on nursing home challenges and strategies will address problems maintaining resident safety and infection control. This work may uncover issues related to disparities, but it will not study the causes of the differences we found in infection and death rates.

Additionally, HHS-OIG has ongoing work focused on the collection and use of data on disparities in COVID-19 cases and outcomes by the Centers for Disease Control and Prevention (CDC). This study will examine data that CDC collects and maintains that can be used to assess racial, ethnic, and socioeconomic disparities in COVID-19 cases and outcomes, as well as how CDC uses those data as part of its activities to address the COVID-19 pandemic. HHS-OIG will also examine CDC's lessons learned about how to best protect communities of color and economically disadvantaged communities in future public health emergencies.

More broadly, our extensive work focusing on nursing homes may be useful as you, Congress, and other stakeholder look for ways to address the significant problems at nursing homes. HHS-OIG has made substantial investments in oversight, enforcement, compliance, and outreach to protect nursing home residents. HHS-OIG has an extensive body of completed and ongoing work and recommendations looking at the vulnerability of nursing home residents to COVID-19 and other emergencies; abuse, neglect, and failures of care in nursing homes; States' oversight of nursing homes; risks to quality of care and well-being for residents in nursing homes.

HHS-OIG investigates potential criminal and civil violations to hold accountable those who victimize residents of nursing homes. HHS-OIG investigates and works with DOJ to resolve False Claims Act cases, which may lead to the subject provider entering into a Corporate Integrity Agreement that contains provisions addressing policies and procedures, training, internal monitoring, and other requirements to improve quality of care. In addition, HHS-OIG may exclude the nursing home or chain from participating in Federal health care programs. HHS-OIG runs the Federal grant program for State Medicaid Fraud Control Units (MFCUs); MFCU investigations and prosecutions of nursing home abuse or neglect cases are a core component of their grant responsibilities. HHS-OIG also engages providers in protecting residents. In July 2020, HHS-OIG staff contacted 493 nursing homes and 236 emergency medical services providers that serve nursing homes. HHS-OIG provided information on how to report concerns about unsafe COVID-19 practices, quality of care, patient abuse, neglect, and health care fraud or misconduct. HHS-OIG is planning future engagements with nursing homes regarding emergency preparedness and response.

Implementation of pending HHS-OIG recommendations would help protect vulnerable residents. Among unimplemented HHS-OIG recommendations related to nursing homes, a top recommendation is that, to ensure that nursing homes are implementing actions to prevent the spread of COVID-19 and that they are protecting residents, CMS should assess the results of infection control surveys of nursing homes and revise surveys as appropriate, and clarify expectations for States to complete backlogs of standard surveys and high priority complaint surveys that were suspended in the early months of the pandemic.

HHS-OIG would be pleased to brief you and your staff on this body of work.

- c) Crowding in nursing facilities was one of the main reasons that COVID-19 was able to spread so quickly to so many residents. I have led efforts here in the Senate to expand**

the Money Follows the Person program, which aims to transfer people from institutional settings to the comfort of their own homes and communities. In your opinion, are programs like Money Follows the Person helpful in preventing this tragedy from happening again in the future?

Throughout my career at HHS-OIG, I have demonstrated commitment to improving home and community-based services (HCBS) to ensure that these services are delivered effectively and efficiently and provide improved quality of life and health. Improving access to, and the quality of, HCBS, such as personal care services, social services for adults, and group homes for people with developmental disabilities, is essential. These services help ensure that the millions of individuals can continue to live independently outside of institutions and nursing facilities. HCBS provide individuals leaving institutional care more options to do so. As with nursing home care, we must ensure that HCBS providers maintain safe, high quality services for beneficiaries. HHS-OIG has ongoing work examining HCBS, including an audit to assess State and provider compliance with health and safety requirements involving Medicaid beneficiaries residing in individualized supported living settings. This review will include an assessment of resident safety measures for infectious diseases such as COVID-19.

Other HHS-OIG work supports strengthening HCBS practices. Our Office of Audit Services conducts extensive audits of State claims for Federal Financial Participation, including audits addressing Money Follows the Person (MFP) expenditures. Further, HHS-OIG has an extensive body of work addressing HCBS in dozens of states under a wide range of Medicaid waivers and in various service settings, including home health, hospice, personal care service, group homes, and adult day centers.

We do not have work focused on the value and role of MFP in supporting beneficiaries who wish to receive home care rather than nursing facility care. HHS-OIG would like to learn more about your interest in this topic to inform our ongoing work planning and further explore how our existing HCBS work may inform for your efforts

Looking toward the future in health care, value-based care models increasingly promote care in home and community settings through in-person home visits, remote monitoring, and other technologies. At-home care is often preferred by patients. An HHS-OIG evaluation of strategies used by Medicare accountable care organizations (ACOs) found that many ACOs provided beneficiaries with a range of at-home services. In 2020, HHS-OIG issued new regulations under the Federal anti-kickback statute and the civil monetary penalties law to promote improved care coordination and value-based care, including arrangements that can facilitate more care in peoples' homes. It will be important to ensure that new models that provide more care in peoples' homes operate as intended for the person's benefit and are not compromised by fraud, waste, or abuse. HHS-OIG's work on telehealth is described in the responses to your next question.

- 2) Telemedicine services have been extremely helpful and popular during the public health emergency. The University of Washington School of Medicine, a leading health provider in my state, has offered telehealth services for its patients across the Pacific Northwest since the 1970s. Over the past five years, the number of people seeking telehealth services has steadily grown to around 21,000 per year in 2019. After the pandemic began, that number ballooned to over 20,000 per month, accounting for approximately 20 percent of all ambulatory visits.**

There have been numerous reports that telehealth fraud has become more and more prevalent in recent years. Just this week, the Department of Justice charged 43 individuals with exploiting more than \$1.1 billion in telemedicine fraud schemes.

Public trust in the health care delivery system is imperative for a successful health care network that provides high quality service, especially during the COVID-19 pandemic.

a) Who, or which demographics, were the main targets of telehealth fraud? What can we do to improve telehealth literacy and security so that people are aware when they are being targeted?

To date, most of HHS-OIG's enforcement in this area has involved "telefraud"—schemes that use phone calls or sham remote visits to engage with a beneficiary to order or prescribe medically unnecessary testing, equipment, or prescriptions. The alleged fraud associated with these schemes is in the billions of dollars and is largely associated with fraud related to medically unnecessary claims for durable medical equipment (DME), various types of laboratory tests, and pain medication.

These telefraud schemes intentionally target Medicare beneficiaries. In four national law enforcement actions, HHS-OIG identified hundreds of thousands of elderly and disabled individuals who were targeted by the schemes and had medically unnecessary items ordered or prescribed on their behalf. During the pandemic, fraudsters are victimizing unsuspecting Medicare beneficiaries and stealing from Federal health care programs through aggressive telemarketing techniques to confuse beneficiaries and take advantage of the growing acceptance of remote care. HHS-OIG remains committed to taking swift action against bad actors who engage in telefraud schemes or seek to exploit telehealth services and remote care.

To spread awareness of scams, HHS-OIG has published materials and fraud alerts on our website and social media and has partnered with Government and private stakeholders to alert Medicare beneficiaries on emerging telefraud scams so they can take steps to protect themselves. For example, we regularly share information with the Senior Medicare Patrol (SMP), which has published specific educational materials related to telefraud scams. HHS-OIG is developing additional educational materials for beneficiaries and doctors about additional practical steps they can take to avoid telefraud scams. Once those materials are public, HHS-OIG will notify your office.

HHS-OIG will continue to assess the need for additional HHS-OIG compliance materials to help providers who want to comply with laws and provide high-quality telehealth services to their patients. More broadly, with respect to improving telehealth literacy, a range of Government and private stakeholders, especially those who interact directly with patients and consumers, can play important roles in educating the public.

HHS-OIG has oversight work underway looking at telehealth in Medicare and Medicaid, described more fully in the response to your next question. Further, HHS-OIG is coordinating with other Offices of Inspector General as part of the Pandemic Response Accountability Committee to plan oversight work related to telehealth issues that affect multiple Federal agencies. Although work planning is ongoing, the expectation is that this work will provide valuable insights into telehealth service delivery and payment across several Federal agencies. These insights may further inform policymakers and other stakeholders about the successes and challenges that span Federal programs. HHS-OIG would be pleased to provide a briefing for you and your staff on this work.

- b) I understand that the Departments of Justice and Health and Human Services operate a joint initiative, the Medicare Fraud Strike Force, to prevent and deter health care fraud around the country. Has the joint initiative been successful in decreasing the volume of fraudulent claims? Is there any room for expansion of scope beyond Medicare to include other government health care programs?**

To protect beneficiaries and recover billions in alleged fraud, HHS-OIG and our law enforcement partners have conducted four successful, large-scale takedowns that have targeted telefraud schemes: [Operation Brace Yourself](#), the [2020 National Health Care Fraud Takedown](#), the [2021 COVID-19 Takedown](#), and the [2021 National Health Care Fraud Enforcement Action](#). These actions were conducted as part of the Strike Force initiative.

These joint enforcement actions can reduce potentially fraudulent claims to Medicare. For example, in the 16 weeks prior to and during the week of Operation Brace Yourself, the 130 DME suppliers that were targets of the takedown submitted \$754 million of claims to the Medicare program and were paid \$389 million by CMS. In the 16 weeks following the takedown, the same 130 DME suppliers that were suspended by Medicare submitted \$279,000 of claims and were paid \$133,000. Furthermore, there was a 48% decrease in Medicare payments for products related to Operation Brace Yourself (primarily DME) and 74 DME suppliers voluntarily withdrew from billing the Medicare program.

The telefraud takedowns mostly involve fraud against Medicare because the schemes specifically target Medicare beneficiaries. However, other Strike Force operations have taken action against fraud that affected other Government health care programs, including Medicaid and TRICARE. We continually monitor fraud trends and share them with our government program integrity partners, including other Offices of Inspectors General and law enforcement partners. Coordinated enforcement is critical to success, and HHS-OIG routinely seeks opportunities to work with law enforcement partners to strengthen oversight and protect programs and patients.

- c) In terms of technology, how can health care and technological providers collaborate in improving security features to stamp out attempts of fraud?**

It is important that new telehealth technologies with potential to improve care and enhance access achieve these goals are not compromised by fraud, abuse, or misuse. HHS-OIG recognizes that the increased demand for telehealth services raise privacy and security concerns as providers and patients adopt new technology for telehealth and other virtual care.

HHS-OIG has recently announced seven reviews addressing telehealth, that endeavor to provide objective findings and recommendations to further inform policymakers and other stakeholders as they consider changing telehealth beyond the public health emergency. HHS-OIG is also currently developing two reviews that will assess security- and privacy-related issues associated with telehealth:

- Medicare Part B Telehealth Services During the COVID-19 Public Health Emergency: HHS-OIG will conduct a series of audits of Medicare Part B telehealth services, including a review of telehealth technology and potential effects of Health Insurance Portability and Accountability Act (HIPAA) waivers during the public health emergency.

- Audit of IHS Telehealth Technologies' Cybersecurity Controls: HHS-OIG is conducting an audit that will determine whether Indian Health Services has implemented cybersecurity controls to protect its telehealth technologies from emerging risks.

Earlier this year, HHS-OIG provided technical assistance to Congress, including the Senate Committee on Finance and your staff, that highlighted potential risks based on high-level early data analyses. In that technical assistance, HHS-OIG identified the following potential safeguards to increase security and minimize risk of telehealth services:

- ensure expanded telehealth technology meets a consistent level of security expectations,
- ensure that security requirements take into account the patient role and potential vulnerabilities and harmonize security requirements as much as possible across service types,
- create a system between provider and patient to verify the provider (e.g., technology verification “handshake” or something similar to multifactor authentication or to the electronic visit verification system for home health and personal care services),
- continue addressing patient access to reliable internet connection to ensure that patients can securely communicate with their providers, and
- ensure training on telehealth-specific health care privacy and security training for providers and staff who provide telehealth services.

HHS-OIG is committed to keeping this Committee, Congress, and other stakeholders informed in instances where significant risks are found that are supported by data and our analysis, audits, evaluations, and investigations. HHS-OIG recognizes the importance of providing timely, independent, and objective information as policymakers consider telehealth expansion or other changes beyond the public health emergency, including potential impacts on security and privacy.

Senator Catherine Cortez Masto

- 1) In response to the COVID-19 pandemic, both Congress and the Department of Health and Human Services (HHS) expanded access to telehealth for a wide range of services. What kind of data and utilization information is the OIG currently working to collect and what will be important for Congress to consider as we seek to make some of these expansions permanent?**

HHS-OIG’s direct access to Medicare data allows for sophisticated monitoring of telehealth claim utilization patterns. By identifying outliers and other patterns, HHS-OIG generates potential leads for investigations or spots potential program integrity risks that would benefit from further oversight. We have been monitoring Medicare claims data since the beginning of the pandemic in spring 2020 via automated reports that are shared with the CMS and our law enforcement partners. HHS-OIG will continue this effort and improve our data analytics by incorporating field intelligence from our law enforcement agents, auditors, and evaluators.

HHS-OIG recently announced seven reviews and issued three reports addressing the telehealth used to provide behavioral health services in Medicaid. Several of these reviews will assess specific aspects telehealth utilization. For example, HHS-OIG is conducting a [data snapshot](#), which will describe the extent to which Medicare beneficiaries had established relationships with providers from whom they

received telehealth services. These recently announced reviews and reports are described in the attached Appendix 2.

Many of these telehealth oversight reports are expected to be completed in calendar year (CY) 2022. As appropriate, HHS-OIG's telehealth oversight will recommend suitable safeguards to help ensure that telehealth operates effectively and efficiently to enhance access; deliver quality health care; improve health outcomes; and mitigate potential fraud, abuse, and misuse.

In instances where HHS-OIG finds significant risks that are supported by data and our analysis, audits, evaluations, and investigations, HHS-OIG is committed to keeping this Committee, Congress, and other stakeholders informed. HHS-OIG recognizes the importance of providing timely, independent, and objective information as policymakers consider telehealth expansion or other changes beyond the public health emergency. We have already provided technical assistance to Congress, including the Senate Committee on Finance, earlier this year that highlight potential risks and safeguards based on high-level, early data analyses.

2) In your opinion, would it be beneficial to extend telehealth access to be able to further study and review the effects that the expanded access to telehealth during the pandemic has had on access, cost, and quality of care?

I recognize the potential positive effects of telehealth expansion. It offers opportunities to increase access to services, decrease burdens for both patients and providers, and enable better care, including enhanced mental health care. [A 2019 HHS-OIG study](#) found that telehealth can be an important tool to improve patient access to behavioral health services. And as we observed in a [rulemaking in December 2020](#), HHS-OIG recognizes the promise that telehealth and other digital health technologies have for improving care coordination and health outcomes.

It is important that new policies and technologies with potential to improve care and enhance access achieve these goals and are not compromised by fraud, abuse, or misuse. HHS-OIG's oversight work referenced in response to your first question can help ensure that the potential benefits of telehealth are realized for patients, providers, and HHS programs.

As HHS-OIG's work and the national conversation regarding telehealth continues, I believe there is a shared goal: ensuring that telehealth delivers quality, convenient care for patients and is not compromised by fraud. If I am confirmed, I look forward to providing objective, independent information to stakeholders and policymakers to help achieve the goal.

3) Recently published OIG reports looked at State Medicaid programs using telehealth to provide behavioral health services and noted the various challenges and opportunities in this space. In one report, OIG recommended that CMS conduct evaluations on the effects of telehealth on access, cost, and quality of behavioral health services and monitor for fraud, waste and abuse in this space. The report stated that CMS did not explicitly state if it concurred with these recommendations, despite that many States believe that telehealth has increased access to care and they are unsure of the impacts it has on quality and cost. Do you foresee any impediment to CMS implementing these recommendations and does Congress have a role to play in carrying out this recommendation?

Consistent with normal HHS-OIG report follow-up processes, CMS has 6 months from the issuance date of the report to submit a Final Management Decision in response to the recommendation. In the Final Management Decision, CMS should provide details about any plans or progress to implement this recommendation and should indicate whether it concurs or non-concurs. HHS-OIG will continue to follow up with CMS on the status of this recommendation through this process. HHS-OIG would be happy to provide you and your staff a briefing on this work and explore ways that Congress might support evaluation of telehealth. Further, HHS-OIG will keep you and your staff updated on the recommendation status following receipt of CMS's Final Management Decision.

4) Recent increases in unaccompanied minors seeking asylum at the southern border, combined with the ongoing COVID-19 pandemic, have strained immigration resources and exposed intolerable conditions in detention facilities. As Inspector General, how will you guide oversight of the Office of Refugee Resettlement's Unaccompanied Children programs?

The safety and care of unaccompanied children in HHS custody has been and remains a key focus for HHS-OIG. If I am confirmed, HHS-OIG will continue to provide independent oversight of the Office of Refugee Resettlement (ORR) Unaccompanied Children (UC) Program, and actionable recommendations for improvements.

Past HHS-OIG work has uncovered significant safety and well-being concerns at the care facilities, and not all of HHS-OIG's recommendations for improvements have been implemented. Earlier this year, we released a [toolkit](#) of insights from our audits, evaluations, and investigations that outlines consequential actions that HHS program officials and care facility administrators can take to ensure the health and safety of unaccompanied children, especially children at new influx care facilities and emergency intake sites—two types of facilities that are not required to be State licensed.

If confirmed, I will guide our work using a dynamic, risk-based approach that will help HHS-OIG anticipate and respond to emerging issues and vulnerabilities with the resources available. To enhance the impact of this work, HHS-OIG will leverage data, modern technology, specialized expertise, and strategic partnerships. I will also further our work in automating our ability to monitor reports of sexual abuse and other Federal crimes committed against unaccompanied children. This will allow HHS-OIG to coordinate more efficiently with ORR, law enforcement partners, and non-governmental organizations to appropriately investigate and respond to allegations. I am also committed to continuing to alert HHS to trends and concerns that HHS-OIG teams have identified from site visits to facilities for unaccompanied children, or through other work.

Two areas of pressing concern are health and safety vulnerabilities in ORR care facilities and ensuring appropriate placement of unaccompanied children. HHS-OIG has been closely monitoring the ORR response to the 2021 surge, including conducting oversight on the ground at care facilities. We have work underway assessing influx facilities and emergency intake sites with regard to background checks, COVID-19 protocols, and case management, including work at Fort Bliss. Other ongoing work includes assessing children's initial placements and subsequent transfers to identify any challenges that ORR and facilities may have encountered in the placement and transfer process. Information on HHS-OIG's completed and ongoing work is available on the [Unaccompanied Children](#) page of the featured topic section of our website. We appreciated the opportunity to brief your staff on HHS-OIG's UC Program work in April 2019 and the continued engagement with your staff since then. We would be happy to provide additional briefings to you and your staff on this issue.

- 5) According to a 2016 GAO report, ORR lacked a process for annually updating and documenting its plan to care for unaccompanied children, including planning for housing and educational, medical, and therapeutic service needs. What are your goals to ensure the Department of Health and Human Services is properly monitoring and documenting care for unaccompanied children in ORR custody?**

After responsibility for unaccompanied children was transferred to HHS by the Homeland Security Act of 2002, HHS-OIG has provided extensive oversight to the ORR UC Program, including issuing 23 reports since 2017. Similar to findings from GAO's 2016 report, HHS-OIG has identified concerns with ORR's oversight of the UC program and provided recommendations to support program improvements, including recommendations related to monitoring and documenting care.

In fiscal year 2021, HHS-OIG released four new reports on the UC Program, and we currently have eight ongoing oversight reviews. If I am confirmed, HHS-OIG will continue its independent oversight of the UC Program, including providing actionable recommendations for program improvements that better protect children. This work and my approach are further described in the preceding response. Although it is up to HHS and care facilities to implement HHS-OIG recommendations, if confirmed, I will continue to ensure that HHS-OIG is actively tracking recommendations that remain unimplemented. In addition, to further my goal to drive positive change, I will oversee the launch of a streamlined, transparent, and interactive approach to provide stakeholders better access to our findings and open recommendations via our public website.

Ranking Member Mike Crapo

- 1) I am concerned about the potential for the work of HHS OIG, and indeed that of all inspectors general, to become politicized, despite their offices' intended independence.**
- a) What is your understanding of your role in reviewing policy decisions made by career officials and political appointees?**

The role of an Inspector General is to oversee programs and operations of the Department; to make recommendations to promote the economy, efficiency, and effectiveness of Department programs; and to prevent and detect fraud and abuse in such programs, acting at all times with independence and objectivity. Under the IG Act, an Inspector General cannot engage in program operating responsibilities. Accordingly, an Inspector General does not make program decisions or substitute her judgement for the discretion of a program official. If I am confirmed, I will provide independent, objective oversight of Department programs and operations consistent with the IG Act.

- b) How will you work to ensure OIG acts as an independent investigator?**

Inspectors General perform an essential public service. They root out fraud, waste, and abuse and help make programs more efficient and effective. Their ability to do that is rooted in their independence and objectivity. Through independence, objectivity, and transparency, Inspectors General help Government better serve the American people. A strong Inspector General makes a stronger department and a stronger, more trusted Federal Government.

One way that I will ensure independence and objectivity, if I am confirmed, is by ensuring that HHS-OIG continues to closely follow the standards for work products, such as audits and evaluations. This means that HHS-OIG will continue to keep an arm's length from the agencies and programs it oversees. The IG Act provides Inspectors General with several means to maintain independence, such as an OIG having its own legal counsel and the ability to hire its own personnel and contract for goods and services. Independence also means that Department officials have to make program decisions without the approval of their Inspector General. If I am confirmed, HHS-OIG will continue to follow the facts wherever they lead and conduct itself in a wholly nonpartisan manner.

Maintaining independence does not mean that HHS-OIG cannot have productive relationships with Department leaders and officials. I meet regularly with Department officials to talk about HHS-OIG's findings and recommendations. I encourage our senior leaders and subject matter experts to do the same with their counterparts. Those relationships are critical to ensure understanding of our work and resultant recommendations and will continue if I am confirmed. When I meet with HHS officials, I often say that they may not always like what we say, but I hope they will take our input as a blueprint for what can be done better.

- 2) **Last year, HHS OIG took an important step towards driving value for American patients from all walks of life with its updates to the Anti-Kickback Statute's (AKS) safe harbor regulations, which will help to facilitate high-quality and dynamic value-based arrangements (VBAs), in addition to bolstering cybersecurity safeguards and adapting to some of the pressing technological needs of the health care system. These safe harbor modernization efforts, however, included a number of exclusions that risk retaining barriers to effective VBAs, medication adherence programs, and other patient-centered initiatives, particularly with respect to medical device and life sciences innovators. While well-intentioned, exclusions along these lines can hinder efforts to promote positive health outcomes and reduce health disparities.**

Can you commit to continuing to engage with my office, along with the offices of other interested Members, to ensure that our vital anti-fraud and abuse laws protect patients while also keeping pace with an evolving and technologically advancing health care ecosystem?

Yes, I can commit to engaging with your office and offices of other interested Members on this issue. Congress intended safe harbor regulations to evolve as the health care industry and technology changed. To this end, HHS-OIG has issued new and modified safe harbors from time to time and annually solicits suggestions from the public on new and amended safe harbors. HHS-OIG's goal is to promulgate safe harbor regulations that protect beneficial arrangements for patients and at the same time protect against fraud and abuse. Safe harbor work is conducted with public input, including through notice-and-comment rulemaking, and in consultation with the Department of Justice (DOJ).

- 3) **Effective coordination among federal agencies enables more efficient and informed responses to policy challenges, as HHS OIG has demonstrated through its partnership with the Department of Justice (DOJ) in overseeing and enforcing important anti-fraud and abuse laws like the Anti-Kickback Statute (AKS).**

a) With respect to this partnership in particular, what role does DOJ play with respect to AKS oversight and enforcement, and how does HHS OIG work with DOJ on this front?

HHS-OIG and DOJ have a long and successful collaboration regarding AKS oversight and enforcement. DOJ has primary responsibility for enforcement of the AKS, which is a criminal statute. DOJ prosecutes criminal cases in Federal court. HHS-OIG's Office of Investigations (OI) investigates AKS cases, often in coordination with other law enforcement partners, including DOJ and the FBI. OI works closely with DOJ and U.S. attorneys to charge and resolve cases and HHS-OIG attorneys frequently consult to provide legal expertise regarding the AKS.

DOJ also brings or intervenes in False Claims Act cases predicated on AKS violations on behalf of the government; HHS-OIG investigates those cases, often in coordination with other law enforcement partners, and is signatory for HHS on settlement agreements. HHS-OIG's other roles with respect to the AKS include negotiating corporate integrity agreements with companies settling AKS cases, issuing advisory opinions and other guidance regarding the application of the AKS, and promulgating safe harbor regulations. HHS-OIG coordinates closely with DOJ on all matters related to the AKS and, as required by statute, consults with DOJ before issuing advisory opinions and safe harbor regulations. HHS-OIG also has administrative enforcement authority to impose civil monetary penalties, program exclusion, or both for violations of the AKS. In this area, we coordinate with DOJ to ensure that the Government is pursuing the most appropriate remedy for the conduct in the particular case.

b) Do you see areas for improvement or opportunity in terms of coordination between HHS OIG and DOJ?

I see tremendous opportunity to continue to build on our outstanding partnerships with DOJ and other law enforcement entities to best combat fraud and protect individuals served by HHS programs from harm. The Health Care Fraud Strike Force model has proven to be successful since the first team launched in March 2007. Strike Force partnerships between HHS-OIG, DOJ, U.S. Attorney's Offices, the Federal Bureau of Investigation, and the Drug Enforcement Administration are a force multiplier that utilize a coordinated and data-driven approach to identifying, investigating, and prosecuting fraud. Since its inception, Strike Force prosecutors have filed more than 2,100 cases charging more than 4,600 defendants who collectively billed Federal health care programs and private insurers approximately \$23 billion; more than 3,000 defendants pleaded guilty and over 390 others were convicted in jury trials; and more than 2,800 defendants were sentenced to imprisonment for an average term of approximately 50 months.

Our coordinated law enforcement operations both remove bad actors from participation in HHS programs through convictions and exclusions and effect widespread change in behavior by serving as a deterrent for others. This coordination has also been critical to OIG's enforcement efforts and other work to address the prescribing and treatment dimensions of the opioid crisis, as discussed in HHS-OIG's testimony before the Senate Committee on Finance in a hearing entitled, [‘OIG Efforts to Address the Prescribing and Treatment Dimensions of the Opioid Crisis’](#) on October 24, 2019.

Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts. As just one example, at its peak, Medicare was billed \$472 million in April 2019 for CPT codes covering genetic testing, and paid out \$111 million. The numbers were similar in May, June, and July, 2019. When we made our first arrest in August as part of an initiative known as Operation Double Helix, which was led by the Health Care Fraud Strike Force, billing dipped to \$154 million, with \$48 million

paid. In October, the month after the coordinated law enforcement takedown, the numbers decreased to \$51 million billed, \$15 million paid, a roughly 87-percent drop in money out the door. That November, Medicare paid out only \$2 million for these codes—a 98-percent drop from the peak of \$111 million 6 months earlier.

HHS-OIG will continue to collaborate closely with DOJ and other law enforcement partners to direct investigative resources to areas of greatest need, and explore new opportunities to expand efforts, to best protect HHS programs and the individuals they serve.

- 4) While HHS OIG has no oversight over Medicare Part D’s programmatic requirements or payment policies, its work to combat fraud and abuse can have implications for Part D beneficiaries, as well as a range of stakeholders across program and the health care system more broadly.**

Given that reports indicate the Administration is unlikely to move forward with implementation of the Rebate Rule finalized in November 2020, does HHS OIG have any plans, at this point, to revisit prescription drug rebate reform, either through potential rulemaking or other policy mechanisms?

The rebate rule, which is a safe harbor rulemaking under the Federal anti-kickback statute, is the subject of ongoing litigation, and I cannot comment on it or any related matters. As a general matter, under the IG Act, HHS-OIG may audit, evaluate, and investigate program vulnerabilities in Medicare Part D and make recommendations to mitigate them. HHS-OIG does not, however, set program policy and implement reforms to the Medicare Part D program; these would be implemented by Congress or CMS, which administers the program.

Understanding what drives high drug spending for programs and beneficiaries is critical and a priority for HHS-OIG. HHS-OIG has conducted, and continues to conduct, a wide range of reviews addressing rebates and other drug-related topics in the Medicare and Medicaid programs. HHS-OIG’s goal is to identify opportunities to reduce drug spending for patients and HHS programs (i.e., Part D, Part B, and Medicaid), while ensuring access for beneficiaries. HHS-OIG does this by focusing on three main areas: (1) determining whether HHS program and patients are overpaying for prescription drugs based on current HHS program and drug reimbursement rules, (2) assessing the impact of current HHS program and drug reimbursement rules on drug spending, and (3) assessing compliance with prescription drug reimbursement statutes and regulations. HHS-OIG would be happy to provide a briefing about our work in this area.

Senator Chuck Grassley

- 1) Recently, the Department of Justice, along with the HHS Office of Inspector General (OIG) and other law enforcement agencies, announced criminal charges against 138 defendants, including doctors and nurses, for over \$1.4 billion in alleged losses. The largest amount of fraud charged – more than \$1 billion – relates to telemedicine services. The second largest amount of fraud charged – more than \$29 million – relate to COVID-19 fraud. These figures are startling and represent lost taxpayer dollars. The Federal government must do all that it can to stop these fraudsters from taking advantage of the COVID-19 pandemic.**

a) Please provide examples of the types of fraudulent conduct identified during HHS OIG's recent enforcement action.

The majority of cases brought in the 2021 National Enforcement Action (NEA) are “telefraud” schemes, which accounted for over \$1.1 billion in allegedly false claims submitted by 43 defendants. “Telefraud” schemes use phone calls or sham remote visits to engage with a beneficiary to order or prescribe medically unnecessary testing, equipment, or prescriptions. Some characteristics of the alleged “telefraud” activities in the NEA include:

- Paying illegal kickbacks and bribes to health care providers in exchange for the referral of Medicare beneficiaries;
- Preying on the elderly via telemarketing and health fairs; and
- Providing orthotic braces, genetic testing, and compounded pain creams that were medically unnecessary, not eligible for Medicare reimbursement, and/or not provided as represented.

The NEA demonstrated the Government’s continued focus on investigating and prosecuting evolving COVID-19 health care fraud and schemes involving the Provider Relief Fund. Examples of alleged fraudulent conduct include:

- Providing COVID-19 tests to Medicare beneficiaries to induce the beneficiaries to provide their personal identifying information and a saliva or blood sample. The defendants are alleged to have then misused the information and samples to submit claims to Medicare for unrelated, medically unnecessary, and far more expensive laboratory tests, including cancer genetic testing, allergy testing, and respiratory pathogen panel tests.
- Misappropriating Provider Relief Fund moneys to spend on personal expenses.

Additionally, the NEA included charges involving sober homes, where defendants allegedly referred patients to substance abuse treatment facilities where they could be subjected to medically unnecessary drug testing, as well as enforcement against defendants related to the illegal prescription and/or distribution of opioids.

b) In your opinion, what are the contributing factors that have caused the increase in Medicare and Medicaid fraud we’ve witnessed during the pandemic?

As with past public health emergencies, the COVID-19 pandemic has resulted in rapid evolution of health care fraud schemes that exploit the exigent circumstances of the moment. Although we are still in the midst of understanding the magnitude of fraud schemes that proliferated during the pandemic, HHS-OIG has received thousands of complaints related to purported COVID-19 fraud. In March 2020, when store shelves were emptied of hand sanitizer, the fraud scams offered “senior care packages” complete with hand sanitizer and a face mask. Later, we saw sham contact tracing to steal personal information. And then fake vaccines before vaccines were approved and available. Most recently, we see people selling fake proof of vaccinations. Additionally, the fraudsters specifically targeted Medicare beneficiaries recognizing that many were isolated at home during many parts of the pandemic.

In addition to exigent circumstances, fraudsters are aware of the increased funding and emergency flexibilities appropriately established to support the pandemic response. The risk of improper payments rises when funds are distributed fast to address an emergency, or rules are waived to help the vast majority of health care providers seeking to provide needed care during a pandemic. As a result, there is

increased risk of payments being calculated incorrectly, not being supported with reasonable and appropriate documentation, or not being paid to eligible providers.

HHS-OIG remains committed to taking swift action against bad actors who exploit the public health emergency. HHS-OIG continually monitors fraud trends—for example, by using our direct access to Medicare claims to spot outliers and aberrant trends—and share them with our Government program integrity partners, including other Offices of Inspectors General and law enforcement partners. This trend information helps identify potential targets and schemes for further investigation.

c) I applaud the Federal government’s efforts to prosecute COVID-19 related fraud, but these are reactive measures. What types of proactive measures can the Federal government take now to prevent fraud before it occurs?

I wholeheartedly agree with the importance of preventing fraud before it occurs. If I am confirmed, I am committed to helping HHS identify proactive measures that can be adopted as new programs are established and existing programs improved. Integrating program integrity features into the programs early provides the best opportunity to prevent fraud before it occurs. In my experience, program integrity can be an afterthought during program implementation, and agencies later struggle to retrofit program integrity measures. To this end, for example, HHS-OIG provided technical assistance as HHS stood up the Provider Relief Fund so that program officials had an understanding of key program integrity risk factors and HHS-OIG insights from prior work on other funding programs. Similarly, HHS-OIG has been providing technical assistance to the Department on program integrity for new programs under the American Rescue Plan. This technical assistance drew from HHS-OIG’s prior oversight work that made recommendations to improve program integrity activities in the Administration for Children and Family’s Child Care and Development Fund (CCDF) block grant program.

Improving the availability and usability of data within programs is key to ensuring that agency officials have needed information to identify and mitigate emerging risks. Although preventing fraud entirely through data analysis may not be possible, improving transparency of program operations based on better data can allow program officials to identify problems early and mitigate the effects of fraud. HHS-OIG has consistently identified the need to improve HHS data operations and governance as part of the [HHS Top Management Challenges](#).

Additionally, more useable and accessible data will support deployment of modern tools to perform key program integrity functions, such as improving how the government authenticates or verifies who it is doing business with or paying. For example, effective deployment of artificial intelligence (AI) is primarily dependent on having access to large datasets that can be analyzed to teach the AI. With better data, programs may be able to deploy AI to assess claims for payments to rapidly identify risks or outliers. HHS-OIG is also assessing how multifactor authentication technology could be used to reduce the effect of medical identify theft, where a health care provider’s identity is stolen to commit health care fraud. Additional authentication may limit the opportunity for criminals to use stolen health care provider identities to bill for wholly fraudulent claims.

HHS-OIG’s collaboration with private-sector stakeholders enhances the opportunities to prevent health care fraud schemes from growing. The Healthcare Fraud Prevention Partnership and National Health Care Anti-Fraud Association are public-private partnerships that foster a proactive approach to preventing fraud through data and information sharing. Together, we examine emerging health care fraud trends and

develop key recommendations and strategies to address them. Enhancing these partnerships and ensuring resources are shared across Federal health care programs, state programs, and private payors help mitigate the spread of fraud schemes and can prevent future losses.

Finally, as a general matter, I would urge that when Congress considers new programs, it also considers commensurate oversight and program integrity resources.

- d) In HHS OIG’s strategic plan to conduct oversight of COVID-19 response and recovery efforts, the OIG has indicated that it plans to “audit whether known cybersecurity vulnerabilities related to networked medical devices, telehealth platforms, and other technologies being used in COVID-19 response has been mitigated.” What is the status of this audit?**

The remediation of known vulnerabilities is key to ensuring IT systems are properly secured from cyberattacks. Ongoing HHS-OIG audits related to known vulnerabilities associated with technologies being used for the COVID-19 response, networked medical devices, and telehealth technologies include:

1. Ongoing audit of HHS Protect and TeleTracking Systems, critical systems that HHS recently implemented to capture important COVID-19 data, such as hospital capacity, utilization, and inventory. The report (restricted distribution) will be issued soon.
2. An issued report in June 2021 entitled [Medicare Lacks Consistent Oversight of Cybersecurity for Networked Medical Devices in Hospitals](#). This work evaluated hospital surveyors’ oversight of networked device security, found that this issue is not sufficiently considered in the survey process, and recommended that CMS address this in its hospital quality oversight. CMS’s final management decision is due to OIG in December 2021.
3. Ongoing audit of the Indian Health Service’s newly implemented telehealth technologies. This audit is in the field work stage.

HHS-OIG continues to review the status of open audit recommendations related to the remediation of known vulnerabilities and plan audits that include follow up work to confirm proper corrective actions. For example, HHS-OIG will begin new cybersecurity audits that will perform network cyber threat hunts at HHS. These audits will determine whether: (1) network defenses are effective to detect and mitigate threats or attacks, (2) there is an active threat on HHS’s or one of its Operating Division’s networks, or (3) there has been a past cyber breach. This work builds on our significant body of cybersecurity work assessing HHS systems.

- 2) Since the COVID pandemic began, I have engaged in oversight on two fronts: (1) the origins of the virus; (2) the connection between the Department of Health and Human Services and the National Institutes of Health with the Wuhan lab and coronavirus research. In my July 27, 2021 Senate floor speech, I challenged the federal government’s failure to oversee grants sent by NIH to EcoHealth which then sub-awarded the money to the Wuhan lab. In that speech, I also challenged the HHS Inspector General’s audit, which focuses on NIH’s compliance requirements and EcoHealth’s as well. I stated, “I expect the Inspector General to be aggressive and unrelenting. Get the records, the emails and the memos. Run the transcribed interviews and question everyone up the leadership chain. Leave no stone unturned and make as much public as possible. If punches are pulled, this audit will be a waste of everyone’s time and taxpayer money. The Inspector General has a tremendous**

responsibility to get this done the right way.” I appreciate your responses to my questions at the September 22, 2021 Finance Committee nomination hearing. I also appreciate our conversation on September 29, 2021 to answer my follow-up questions on this work. With respect to the verbal answers that you provided to me on our September 29 call, I request that you provide written answers to the same in the interest of the Finance Committee’s work and for the purposes of public transparency.

- a) **Based on your testimony, I understand that your work does not include identifying the source of the coronavirus. I want to make sure that I understood your testimony with respect to gain of function research. Will your audit determine if gain of function research occurred at the Wuhan Institute of Virology and whether it was connected to taxpayer money? If not, in order to understand whether NIH and its components followed federal rules, don’t you have to determine if gain of function research was performed?**

HHS-OIG’s ongoing audit, [Audit of National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees](#) is designed to assess whether NIH monitored grants to EcoHealth Alliance (EcoHealth) in accordance with Federal regulations and whether EcoHealth similarly provided oversight to ensure compliance by its sub-awardees. The audit will not examine the origins of coronavirus and will not assess research to determine whether gain of function research occurred during the grant performance period. For grants awards that may have included a specific prohibition of gain of function research, the audit will examine the oversight and monitoring activities performed by NIH and EcoHealth to ensure that the grantees and subgrantees adhered to the grant requirements.

HHS-OIG has coordinated this audit with the Government Accountability Office (GAO). They are performing additional oversight specific to gain-of-function research that will complement our audit. HHS-OIG will continue to closely coordinate with GAO and will ensure that our collective work provides the Senate Committee on Finance and Congress with independent, objective information about this issue.

In July 2021, HHS-OIG provided a scope and methodology briefing for your staff regarding this audit. We would be happy to provide additional briefings for you and your staff.

- b) **Do you plan to run any transcribed interviews of government employees and EcoHealth employees? Have you done so already?**

For this audit, the team held virtual meetings with officials at NIH and NIH’s subcomponent, the National Institute of Allergy and Infectious Diseases (NIAID). In addition, the audit team held in-person meetings with EcoHealth officials. As standard audit practice, the interviews are documented in writing by the audit team and kept as part of the audit file. None of the interviews were recorded. As needed, HHS-OIG may request additional interviews of NIH or EcoHealth officials as HHS-OIG continues to conduct the audit.

- c) **I asked you about how much taxpayer money had been sent to EcoHealth for coronavirus research in China. At the hearing, you said you didn’t have those numbers yet, do you now?**

Based on information collected for the audit referenced in the preceding responses, NIH has awarded EcoHealth approximately \$8 million from October 2014 to September 2021. The audit is still ongoing and HHS-OIG is still assessing the specifics of the EcoHealth awards. The technical nature of the grant awards does not provide for an easy classification as to whether the research is specifically for coronavirus. However, based on award titles and descriptions of planned research, it appears that of the \$8 million, approximately \$3,750,000 is for coronavirus research and \$4,210,000 could be coronavirus related research. In addition, EcoHealth made subawards to two Chinese organizations: Wuhan Institute of Virology was awarded approximately \$600,000 and Wuhan University School of Public Health was awarded approximately \$200,000. Both of these subawards relate to the \$3,750,000 awarded for coronavirus research.

d) And finally, I asked about why you decided to do an audit versus an investigation. Can you explain that decision in more detail and under what circumstances an investigation would be opened?

HHS-OIG evaluates specific oversight work through an Engagement Committee. This committee meets weekly to assess potential work and includes representatives from all HHS-OIG components, including our Office of Investigations (OI). When the Engagement Committee assesses information regarding new work that assessment includes representatives from OI, which is the component that reviews to determine whether there are colorable violations of law that warrant criminal or civil investigations. For the specific work related to NIH and EcoHealth grants, HHS-OIG's Engagement Committee determined that an audit was appropriate based on the information it had at the time.

As with all of our oversight work, HHS-OIG continually assesses the specific facts and circumstances as oversight work is conducted. HHS-OIG's Office of Audit Services (OAS) has expertise in identifying potential referrals to OI for conduct such as grant fraud. HHS-OIG does not operate in silos and OAS teams may consult with OI investigators to assess specific facts and circumstances as warranted. To the extent that the audit teams and OI determine that a referral is appropriate (based on the specific facts and circumstances of the particular matter), OAS would make a referral and OI would begin an investigation.

3) Based on concerns raised by Congress, NIH, and other Federal law enforcement agencies, OIG identified four priority areas for NIH oversight in their FY2022 budget request: (1) cybersecurity protections, (2) compliance with federal requirements and NIH policies for grants and contracts, (3) integrity of grant application and selection processes, and (4) intellectual property and research integrity. OIG recently released a report that found NIH did not consider national security risks when permitting and monitoring foreign principal investigators' access to U.S. citizens' genomic data. NIH did not concur with all of OIG's findings. Given that we still do not know the origins of COVID-19 and the startling information that continues to be released on NIH's involvement with institutions associated with the Chinese Communist Party, where does auditing and investigating relationships, financial or otherwise, between HHS and its subcomponents with problematic foreign governments and the potential information sharing between them fall in your list of priorities to tackle?

As an independent, objective oversight and enforcement agency, HHS-OIG follows the facts wherever they lead. To do so, HHS-OIG continually assesses risks to HHS that may jeopardize the economy, efficiency, effectiveness, and integrity of HHS programs. Through this approach of assessing

vulnerabilities, HHS-OIG is aware of increased risks posed by foreign actors in a number of areas, including health care fraud, cybersecurity, and medical research. If confirmed, I am committed to ensuring HHS-OIG continues to assess and address, as appropriate, risks to HHS programs due to inappropriate foreign influence that are within our jurisdiction as a top priority.

Our commitment to addressing these risks is exemplified by HHS-OIG's recent enforcement and oversight work that helps ensure the integrity of taxpayer-funded medical research against foreign threats. Although inappropriate foreign influence associated with taxpayer-funded medical research is a high-profile, complex issue, the cases under HHS-OIG's purview all involve aspects of grant fraud—which HHS-OIG has extensive experience in investigating. Oversight and enforcement of grant fraud and related grant program integrity is an HHS-OIG priority.

Our grant fraud investigations with a foreign influence nexus often involve close collaboration with our law enforcement partners at the Department of Justice, the Federal Bureau of Investigation (FBI), and other Offices of Inspector General, as well as HHS awarding agencies and the Office of National Security (ONS). We also coordinate with various other agencies to protect the integrity of medical research. In some instances, we work on matters with the FBI's Joint Terrorism Task Forces and National Cyber Investigative Joint Task Force, the National Counterintelligence Taskforce, the Department of Homeland Security, and components at FBI Headquarters and local field offices. When appropriate, we work with NIH and ONS to develop follow-up approaches and/or mitigating strategies. Foreign influence research cases are investigated by the HHS-OIG in a similar manner to other grant fraud matters, with coordination and awareness of potential law enforcement sensitivities handled by our partners and other agencies. HHS-OIG is not involved in gathering counterintelligence data pertaining to inappropriate foreign influence.

In addition to the NIH audit referenced in your question, HHS-OIG has also recently issued five audits and studies to improve NIH vetting of peer reviewers, improve NIH policies and procedures related to foreign conflicts of interest, and review NIH grantee institutions' actions to strengthen policies to protect intellectual property and research integrity.

HHS-OIG briefed your staff twice in July 2021 on recent work in this area, including CMS's assessment of national security risks to genomic testing data and our ongoing audit related to NIH and EcoHealth. In addition, I wanted to thank you for your leadership in this area and for holding a hearing entitled '[Foreign Threats to Taxpayer-Funded Medical Research: Oversight Opportunities and Policy Solutions](#)' on June 5, 2019 where HHS-OIG testified on foreign influence before the Senate Committee on Finance. The hearing was an excellent opportunity for HHS-OIG to discuss our work, in conjunction with HHS and law enforcement partners, to protect taxpayer-funded medical research. I look forward to continuing to work with you and your staff on this important topic.

Senator John Thune

- 1) As you know, in South Dakota, there have been far too many challenges with the Indian Health Service (IHS). This includes specific instances of abusive providers and facilities that fail to meet safety standards, as well as overall concern about the quality of care received there.**

I appreciate the work that OIG has done thus far to examine these issues. If confirmed, how would you prioritize IHS in your work plan? How do you balance the need for proactive reviews versus those that are responsive to specific complaints?

HHS-OIG has a longstanding commitment to providing impactful oversight of Indian Health Service (IHS) to help ensure the quality and safety of services provided to the American Indian and Alaska Native community. If confirmed, I will continue that commitment.

Prioritizing work, including balancing proactive and responsive reviews, is part of our work planning process. HHS-OIG work is developed and considered through a process by which an Engagement Committee consisting of the Deputy Inspectors General for each HHS-OIG component carefully considers new work proposals with an eye toward ensuring that HHS-OIG's work has the greatest impact and makes the best use of limited resources. HHS-OIG's work planning process is dynamic, and adjustments are made throughout the year to meet priorities and to anticipate and respond to emerging issues with the resources available. If I am confirmed, HHS-OIG will continue to plan new oversight work based on risk assessment and focus on key vulnerabilities. We will leverage data, modern technology, specialized expertise, and strategic partnerships to conduct oversight and develop actionable recommendations.

HHS-OIG work has identified critical challenges that hinder IHS's ability to provide quality care, ensure sound management of Federal funds, and comply with standards. IHS has taken significant action to address the recommendations provided in our reviews.

During Fiscal Year 2021, we released seven reviews focused on IHS-funded care, including on topics such as adverse events, maternity care, opioids, and patient protection policies. Most recently, we released a [report](#) finding that IHS use of critical care response teams helped to meet facility needs during the COVID-19 pandemic. The report also provides recommendations to further leverage the successes of the critical care response team model in support of IHS's broader care improvement efforts.

HHS-OIG has six additional reviews of IHS-funded care underway. This ongoing work will address such issues as whether IHS-operated facilities and tribally operated facilities met background verification requirements for employees, contractors, and volunteers in contact with children and IHS's coordination of the distribution, allocation, and administration of the COVID-19 vaccine to Tribal Health Programs. Information about our completed and ongoing IHS reviews and recent enforcement actions is available on the [Indian Health and Human Services](#) featured topic page of our website. HHS-OIG would welcome the opportunity to provide you and your staff briefings on this work.

2) Thank you for OIG's active engagement and responsiveness on projects related to telehealth and the pandemic. As we consider whether longer-term policy decisions need to be made on this issue, can you provide additional commentary to the committee about the timelines for the various reports the agency is working on?

Thank you for recognizing HHS-OIG's commitment to conducting oversight of telehealth. HHS-OIG has announced seven reviews and issued three reports addressing telehealth used to provide behavioral health services in Medicaid. We expect the remaining seven telehealth oversight reports to be completed in calendar year 2022, starting with [Data Snapshot: Review of Beneficiaries Relationships With Providers for Telehealth Services](#).

HHS-OIG is committed to keeping the Senate Committee on Finance, Congress, and other stakeholders informed in instances where HHS-OIG finds significant risks that are supported by data and our analysis, audits, evaluations, and investigations. HHS-OIG recognizes the importance of providing timely, independent, and objective information as policymakers consider telehealth expansion or other changes beyond the public health emergency. We have already provided technical assistance to Congress, including the Senate Committee on Finance, earlier this year that highlight potential risks based on high-level, early data analyses.

HHS-OIG looks forward to continued engagement with the Senate Committee on Finance on our telehealth oversight and enforcement work.

3) HRSA has informed my office that it referred six pharmaceutical manufacturers to OIG for failing to provide 340B discounts to contract pharmacies. While I trust that you cannot divulge the details of a matter under active review, can you provide any additional context or timeline for the when the agency might complete the review and issue a decision?

I am somewhat limited in what I can share at this time regarding the 340B referrals issue, but I hope the following information is helpful.

HHS-OIG can confirm that we received the six referrals from HRSA on September 22 and are reviewing them. When considering whether to impose Civil Monetary Penalties (CMPs), HHS-OIG carefully reviews the applicable facts and available evidence relating to each matter. Based on the facts and evidence, HHS-OIG makes a decision about whether to pursue a CMP. General information on the CMP process can be found in HHS-OIG's CMP regulation at [42 CFR 1003](#), and more specific information about the CMPs relating to the 340B program can be found in the [340B ceiling price and CMP final rule](#). Unfortunately, HHS-OIG cannot discuss its ongoing review of the referrals, and HHS-OIG is not able to provide a timetable for review and decision-making. Our staffs have been in contact on this issue as recently as September 2021. We will keep you and your staff updated should there be any new information we are able to share on the referrals matter.

HHS-OIG also has an established body of public reports focused on 340B issues. We would welcome the opportunity to provide a briefing on our 340B related work. For example:

- some of our past work [identified issues](#) with whether 340B entities were getting the discounts required by law and HRSA's ability to oversee the 340B program,
- HHS-OIG has looked at 340B [duplicate discounts with Medicaid](#), and
- HHS-OIG continues to recommend increased transparency for States to ensure compliance and that States get the rebates to which they are entitled.

Senator Richard Burr

1) Oversight is an important function of the Congress and I look forward to working with you, should you be confirmed, to safeguard federal programs and their beneficiaries from waste, fraud, and abuse. In order to work together, however, we need to have open lines of communication. Do you commit to providing me and my staff with information or documentation we request within a specified timeframe?

I agree that open lines of communication are critically important. If confirmed, I commit to respond to all congressional requests within my authority under the IG Act and other applicable statutes. HHS-OIG endeavors to be timely and as responsive as possible to all requests from Congress for information. If I am confirmed, I commit to continuing that practice. HHS-OIG strives to meet deadlines and regularly coordinates with Committee and member staff to set reasonable timeframes for responses. For both pragmatic and legal reasons, HHS-OIG cannot serve as a conduit between Congress and the Department for information or document requests. It is important that HHS-OIG's maintain its independence, and there are statutory and other legal limits on information that HHS-OIG releases.

- 2) **Currently, Congress is undergoing a partisan mad-dash to pass transformational legislation that would radically increase the federal government's role in the daily lives of Americans. These proposals would dramatically increase spending on health programs – on top of the more than \$1.5 trillion in existing annual HHS spending – without so much as a Senate hearing.**

Ms. Grimm, if you are confirmed and these efforts are successful, you will have the unenviable task of investigating the Department at a time when unprecedented amounts of taxpayer funds are being spent and new programs are being implemented in the midst of responding to a once-in-a-century pandemic. What specific steps will you take to ensure that the Office of the Inspector General is able to enhance its oversight capacity to keep pace with such an extreme influx of federal resources that could have immediate impact on the American people? Will you provide regular reports to Congress on the expenditures of these funds?

I share your concern with the need to keep pace, and enhance oversight, to meet a growing portfolio of HHS programs. HHS-OIG has deep experience with oversight of large new programs and conducting work to ensure that they work as Congress intends. For example, after the passage of the Affordable Care Act, we conducted extensive oversight of issues ranging from eligibility for marketplace insurance to accurate subsidy payments, program management, and security of data. More recently, for example, we are conducting a series of audits of distributions from the Provider Relief Fund. HHS-OIG will continue monitoring new programs and providing regular reports to Congress on findings and recommendations from this oversight work. Moreover, in instances where HHS-OIG finds significant risks that are supported by data and our analysis, audits, evaluations, and investigations, HHS-OIG is committed to keeping this Committee, Congress, and other stakeholders informed. HHS-OIG recognizes the importance of providing timely, independent, and objective information to policymakers. As a general matter, I would urge that when Congress considers new programs, it also considers commensurate oversight and program integrity resources.

In my current role, and if I am confirmed, HHS-OIG will continue to plan new oversight work based on risk assessment and focus on key potential vulnerabilities. To enhance the impact of this work, we will leverage data, modern technology, specialized expertise, and strategic partnerships to conduct oversight and develop actionable recommendations focused on high-risk programs and operations. We will use advanced data analytics and multidisciplinary, state-of-the-art investigative techniques to maximize our limited resources and bolster program integrity in HHS programs and services.

Senator Patrick J. Toomey

- 1) **The Office of Inspector General (OIG) at the Department of Health and Human Services (HHS) has previously reported on the pervasiveness of improper payments within the Medicaid program, failure by the Centers for Medicare & Medicaid Services (CMS) to adequately recoup Medicaid overpayments, and recommendations for improving upon these program integrity measures.² Despite OIG's findings and recommendations, the improper payment rate remains persistently high in Medicaid. In 2020, CMS estimated that improper payments accounted for 21.35% of federal program expenditures, and for the 10 years prior, the improper payment rate was routinely above 9%.³**

Congressional Democrats are now in the process of drafting and marking up a multi-trillion dollar legislative package that would make substantial benefit expansions to the existing Medicaid program and establish a look-a-like program for certain individuals in non-expansion states. Such expansions certainly risk exacerbating fraud, waste, and abuse, especially since the proposals are unaccompanied by long-term, structural reforms to address program solvency.

- a) **While Congress still lacks a comprehensive understanding of the extent to which specific factors, such as eligibility errors and documentation mistakes, contribute to improper payments, it is nevertheless clear there remain critical gaps in program integrity. Based on OIG's previous findings, do you believe current oversight incentives for state Medicaid programs are sufficient?**

I share your concern about the Medicaid error rate and addressing it is a top HHS-OIG priority. The high error rates indicate that the current oversight incentives for state Medicaid programs are not working as intended. More work is needed to better understand recent program changes directly related to how CMS measures Medicaid improper payments and how CMS works with states to address the causes of the errors. CMS's Payment Error Rate Measurement (PERM) program measures Medicaid and CHIP improper payments in all 50 States and the District of Columbia annually and produces a national improper payment rate for each program. In 2017, CMS published a new final rule implementing substantive changes to the PERM program that, among other things, were aimed at improving program integrity and promoting State accountability through policy and operational improvements.

These changes were a step in the right direction and have produced a more realistic picture of the beneficiary eligibility errors that are occurring at the State level. This estimated error rate increased since the reintegration of beneficiary eligibility testing in 2019. Based on the CMS PERM regulation, States should be taking action to correct the problems causing high error rates specific to their state programs.

HHS-OIG is currently conducting three audits that will assess the adequacy of the PERM program by determining the accuracy of determinations for the eligibility, fee-for-service, and managed care components of the PERM error rate. The results of this work may identify ways in which CMS and states can improve PERM and address causes of the high improper payment rate. HHS-OIG would be happy to brief you and your staff on this work.

² <https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2020.pdf>

³ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicaid-and-CHIP-Compliance/PERM/PERMErrorRateFindingsandReport>

b) What are the most significant, outstanding recommendations that OIG has previously made to CMS with regard to improving the state of improper payments and overpayments, and what justifications has CMS provided for not implementing these recommendations?

HHS-OIG has a large body of work assessing several of the major causes of high Medicaid improper payment rates. For example, HHS-OIG audits have identified substantial improper payments identifying significant errors with State Medicaid eligibility determinations. The Senate Committee on Finance provided HHS-OIG with a much-appreciated opportunity to discuss our work on Medicaid beneficiary eligibility determinations and what more can be done to secure the future of this important program at an October 30, 2019 hearing, entitled '[Medicaid: Compliance with Eligibility Requirements.](#)' Additionally, HHS-OIG has conducted several studies assessing state Medicaid agency provider screening and enrollment. Finally, HHS-OIG work has found that CMS has not always recovered the overpayments from state Medicaid agencies identified by HHS-OIG audit reports.

The following information provides examples of unimplemented recommendations made to CMS or specific state Medicaid agencies for three categories of work that have significant connection to improper payments and overpayments: Medicaid eligibility, provider screening and enrollment, and overpayment collection. [OIG's Compendium of Unimplemented Recommendations](#) includes more detail on our Medicaid unimplemented recommendations and HHS-OIG is happy to provide you and your staff with a briefing on any of this work.

Medicaid Eligibility

HHS-OIG audited four States' (New York, California, Colorado, and Kentucky) Medicaid eligibility determinations and found that during 2014 and 2015 Medicaid payments were made on behalf of 109 of 460 sampled newly eligible beneficiaries and 98 of 515 sampled non-newly eligible beneficiaries who did not meet or may not have met Medicaid eligibility requirements. On the basis of our sample results, we estimated that the four States made Federal Medicaid payments on behalf of newly eligible beneficiaries totaling almost \$1.4 billion for more than 700,000 ineligible or potentially ineligible beneficiaries. We also estimated that the four States made Federal Medicaid payments on behalf of non-newly eligible beneficiaries totaling more than \$5 billion for almost 5 million ineligible or potentially ineligible beneficiaries.

A majority of HHS-OIG's recommendations to the States addressed the deficiencies related to our findings. Although the States concurred with all 31 recommendations, 18 recommendations remain unimplemented. Specifically, as of 2021, most States have not provided responses to our recommendations to demonstrate that:

- eligibility caseworkers accurately input case actions and properly verify eligibility requirements (12 unimplemented recommendations),
- eligibility verification systems are improved to properly and timely verify all eligibility information (3 unimplemented recommendations), and
- additional policies and procedures are developed to produce more accurate eligibility determinations and to resolve eligibility discrepancies timely (3 unimplemented recommendations).

States' progress in implementing these recommendations varies.

Provider Screening and Enrollment

Provider screening problems are a significant contributing factor to the high Medicaid PERM error rates. HHS-OIG has a noteworthy set of unimplemented recommendations related to Medicaid provider screening and enrollment. Across four reports, there are a total of 17 open recommendations.

We have six outstanding recommendations to CMS from HHS-OIG's evaluation [States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries](#) (OEI-03-19-00070), issued in March 2020. These are that CMS should:

1. recover from States the Federal share of inappropriate fee-for-service Medicaid payments associated with terminated providers,
2. implement a method to recover from States the Federal share of inappropriate managed care capitation payments associated with terminated providers,
3. follow up with States to remove terminated providers that HHS-OIG identified as inappropriately enrolled in Medicaid,
4. confirm that States do not continue to have terminated providers enrolled in their Medicaid programs,
5. safeguard Medicaid from inappropriate payments associated with terminated providers, and
6. review States' contracts with MCOs to ensure that they specifically include the required provision that prohibits terminated providers from participating in Medicaid managed care networks.

We have four outstanding recommendations from HHS-OIG's evaluation [Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries](#) (OEI-05-19-00060), issued in March 2020. These are that CMS should:

1. take steps to disallow Federal reimbursements to States for expenditures associated with unenrolled MCO network providers, including seeking necessary legislative authority;
2. work with States to ensure that unenrolled providers do not participate in Medicaid managed care and assist States in establishing ways to do so;
3. work with States to ensure that they have the controls required to prevent unenrolled ordering, referring, or prescribing providers from participating in Medicaid fee-for-service; and
4. work with States to ensure that they are complying with requirements to collect identifying information and ownership information on Medicaid provider enrollment forms.

We have three outstanding recommendations from HHS-OIG's evaluation [Problems Remain for Ensuring All High-Risk Medicaid Providers Undergo Criminal Background Checks](#), OEI-05-18-00070 (July 2019). These are that CMS should:

1. ensure that all States fully implement fingerprint-based criminal background checks for high-risk Medicaid providers,
2. amend its guidance so that States cannot forego conducting criminal background checks on high-risk providers applying for Medicaid that have already enrolled in Medicare unless Medicare has conducted the checks, and
3. compare high-risk Medicaid providers' self-reported ownership information to Medicare's provider ownership information to help States identify discrepancies.

We have four outstanding recommendations from HHS-OIG's evaluation [Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented](#), OEI-05-13-00520 (May 2016). These are that CMS should:

1. help States implement fingerprint-based criminal background checks for all high-risk providers,
2. develop a central system by which States can submit and access screening results from other States,
3. strengthen minimum standards for fingerprint-based criminal background checks and site visits, and
4. work with States to develop a plan to complete their revalidation screening in a timely way.

CMS responses to each of these reports and recommendations vary, and so has its progress in implementing the recommendations.

CMS Uncollected Medicaid Overpayments

Although uncollected overpayments are not part of the PERM error rate, CMS's failure to collect and States' failure to pay illustrates a significant financial stewardship vulnerability in the management of the Medicaid program. In a [December 2018 audit report](#), HHS-OIG found that CMS had recovered about \$900 million of the \$2.7 billion in Medicaid overpayments identified in prior HHS-OIG audit reports issued to State Medicaid agencies. However, CMS had not collected the remaining \$1.8 billion. In response, CMS informed us that they continue to explore options for improving the timeliness of recovering identified overpayments.

- c) What are the greatest obstacles for OIG when it comes to monitoring improper payments and overpayments within Medicaid, and what steps, if any, does OIG plan to take going forward to improve its abilities to conduct oversight within Medicaid?**

Two of the most significant obstacles for monitoring improper payments relate to: (1) access to complete and accurate Medicaid data and (2) challenges involving State-level systems.

Effective oversight of Medicaid requires access to complete and accurate data. In an effort to improve the completeness and accuracy of Medicaid data, CMS established the Transformed Medicaid Statistical Information System (T-MSIS). Although access to Medicaid payment data made by States has improved for Medicaid fee-for-service payments, continued improvement is needed. Most States are not providing complete or accurate payment data in T-MSIS for managed care payments to providers. The lack of encounter data continues to be a challenge for overseeing States that heavily rely on managed care.

In addition to challenges related to complete and accurate data, HHS-OIG has continually found that States experience challenges in implementing the appropriate systems needed to properly administer their Medicaid programs and maintain the necessary documentation to support Medicaid services claimed for reimbursement. HHS-OIG encounters these same challenges during audits because the lack of developed systems and missing documentation can sometimes impede our ability to properly assess whether overpayments exist and to accurately quantify the overpayment amounts. For example, in prior audits of four States' Medicaid eligibility determinations, we found that Medicaid payments were made on behalf of 31 of 460 sampled newly eligible beneficiaries and 78 of 515 sampled non-newly eligible beneficiaries who may not have met Medicaid eligibility requirements. In these instances, because States did not maintain all of the necessary documentation and their eligibility verification systems were

underdeveloped, we were not able to determine whether some beneficiaries were eligible for Medicaid, and whether overpayments related to these beneficiaries truly existed.

HHS-OIG has long been at the forefront of measuring, monitoring, and recommending actions to prevent improper payments. HHS-OIG's future work will continue to identify root causes for improper payments and feasible action steps to reduce the percentages. To this end, HHS-OIG is crafting a comprehensive multidisciplinary strategy to will target three areas: (1) Medicaid payments made to managed care organizations for beneficiaries who are concurrently enrolled in multiple States; (2) the adequacy of the eligibility and other components of the PERM program review, as well as CMS's oversight of the corrective action plans that States submit to address the causes of improper payments; and (3) States' processes to screen providers for enrollment in the Medicaid program, along with the inappropriate enrollment of terminated providers. In addition, HHS-OIG will continue to review and report on HHS's annual improper payment information as required by the Payment Integrity Information Act. We are happy to brief you and your staff on this strategy and on any work related to this issue.

Senator Bill Cassidy

1) If confirmed, how would you plan to leverage artificial intelligence and machine learning to address fraud, waste, and abuse in HHS programs? Are there particular data where these tools are best suited or should be prioritized?

If confirmed, I am committed to expanding HHS-OIG's use of sophisticated data analytics, including leveraging artificial intelligence (AI) and machine learning (ML), to proactively monitor and address fraud, waste, and abuse in HHS programs. Currently, HHS-OIG uses AI and ML to assist aspects of our oversight and enforcement. Primarily, we use advanced data analytics and AI to assess risk more effectively across HHS programs and geographic locations, and to efficiently deploy resources and increase the impact of our oversight and enforcement. In deploying AI and ML capabilities, HHS-OIG follows best practices to ensure that solutions are responsible, equitable, traceable, reliable, and governable.

HHS-OIG has successfully leveraged AI and ML to support oversight of HHS grants and contracts. Specifically, HHS-OIG developed a Grants and Acquisitions Analytics Portal (GAP) that streamlines access to and delivers a comprehensive view of HHS awards and single audit findings. We implemented ML and advanced AI capabilities, including neural networks and text mining, to identify audit findings buried in millions of pages of A-133 single-audit reports. The impact of this effort was immediate. The time needed for auditors' and investigators' researching has been reduced from a matter of months to minutes.

HHS-OIG has also deployed predictive models that use AI to assign risk scores to Medicare providers for professional services, prescribing, home health, hospice, and pharmacies. Results from these models assist HHS-OIG in identifying targets for investigation as well as in assessing highest risk among providers that are already known to investigators.

The size of the HHS program portfolio continues to increase, health care systems are becoming more complex, and fraud cases are becoming more sophisticated. These factors—accompanied with a significant increase in the amount of health care data—push HHS-OIG to streamline and automate time-consuming and manual analytic and business processes. If confirmed, I will continue to invest in our data and analytics infrastructure and improve capabilities that support AI, ML, natural language processing,

robotics process automation, and predictive analytics. Further investment in cutting-edge technology for data will equip HHS-OIG's teams with the ability to keep up with the growing size and complexity of HHS programs, especially Medicare and Medicaid.

In the near future, HHS-OIG is prioritizing deploying text analytics capabilities to draw insights from Medicaid managed care contracts, using predictive coding to support document review in preparation for prosecutions of health care fraud, and automating audit process related to assessments of the quality and accuracy of Medicare and Medicaid claims.

APPENDIX 1: HHS-OIG Behavioral Health Reviews

HHS-OIG’s Recently Published Reports on Behavioral Health

The following table contains a description of HHS-OIG’s recently published reports related to behavioral health. Work related to behavioral health and telehealth is listed in Appendix 2.

	Title of Review	Description	Issued
1	<u>Behavioral Health—Medication-Assisted Treatment Viewer</u>	The Behavioral Health–Medication-Assisted Treatment Viewer (BH-MAT) is a web mapping application that combines publicly available data to policymakers and program administrators to provide additional analysis for making decisions to improve access to medication-assisted treatment (MAT) for those with opioid use disorder.	May 2021
2	<u>Choctaw Nation of Oklahoma Made Progress Toward Meeting Program Goals During the First Year of Its Tribal Opioid Response Grant</u>	The Choctaw Nation met some program goals for its Tribal Opioid Response grant during the first grant year. Specifically, the Choctaw Nation met program goals in the areas of prevention and recovery. The Choctaw Nation also made progress toward meeting treatment program goals but encountered some challenges that prevented it from increasing the availability of MAT services for Tribal members within its health care system.	January 2021
3	<u>New York Provided Projects for Assistance in Transition From Homelessness Grant Services to Ineligible Individuals and Did Not Contribute Any Required Non-Federal Funds</u>	New York did not always comply with Projects for Assistance in Transition From Homelessness (PATH) program requirements. Specifically, 7 of the 50 consumers we sampled lived in permanent housing settings and documentation in their case files did not indicate that they continued to need PATH services to prevent a recurrence of homelessness. In addition, New York did not meet its funding obligation for non-Federal contributions to its PATH program and did not have written agreements with PATH providers, as required.	December 2020
4	<u>In Selected States, 67 of 100 Health Centers Did Not Use Their HRSA Access Increases in Mental Health and Substance Abuse Services Grant Funding in Accordance With Federal Requirements</u>	Most health centers in the 30 States did not use their AIMS (Access Increases in Mental Health and Substance Abuse Services) grant funding in accordance with Federal requirements and grant terms. Sixty-seven of the 100 health centers in our sample did not meet mental health and substance use disorder service expansion requirements (30), claimed unallowable costs (34), and did not properly allocate salaries and other expenditures to their AIMS grants (34).	November 2020
5	<u>Opioid Treatment Programs Reported Challenges</u>	Opioid treatment programs (OTPs) reported a variety of: (1) challenges they have encountered during the COVID-19 pandemic and (2) actions they have taken to address those challenges while	November 2020

	Encountered During the COVID-19 Pandemic and Actions Taken To Address Them	ensuring the continuity of needed services and protecting the health and safety of their patients and staff.	
6	HRSA’s Monitoring Did Not Always Ensure Health Centers’ Compliance With Federal Requirements for HRSA’s Access Increases in Mental Health and Substance Abuse Services Supplemental Grant Funding	The Health Resources and Services Administration (HRSA) followed its policies and procedures for awarding AIMS grants but did not always follow its policies and procedures when monitoring health centers’ compliance with supplemental funding requirements. Specifically, HRSA did not follow its policies and procedures when monitoring health centers’ progress toward meeting AIMS grant award conditions related to ongoing and one-time funding and did not always respond timely to health centers’ requests to carry over grant funds.	July 2020
7	SAMHSA’s Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply With Some Federal Requirements	The Substance Abuse and Mental Health Services Administration (SAMHSA) performed inspections at selected OTPs but did not: (1) meet its goal for the number of OTPs it would inspect, (2) take actions to address accreditation bodies’ noncompliance with survey requirements, or (3) determine whether OTPs complied with the Federal standards when patient charts were incomplete. In addition, SAMHSA reviewed accreditation bodies’ survey reports, but the reports were inconsistent and did not contain sufficient information to determine whether the OTPs met the Federal standards. Finally, SAMHSA’s evaluations of accreditation bodies’ accreditation elements were not documented or retained.	March 2020
8	ACOs’ Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program	This report highlighted high-performing Medicare Accountable Care Organizations’ strategies to address behavioral health needs (among other strategies), including recruiting behavioral health providers and integrating behavioral and physical health care into primary care settings.	July 2019

HHS-OIG’s Ongoing Work

The following table contains a description of HHS-OIG’s ongoing behavioral health audits and evaluations.

	Title of Review	Description	Expected Issuance
1	Medicare Part B Payments for Psychotherapy Services (Including	In 2020, Medicare paid \$1 billion for psychotherapy services. We have a series of audits under way at selected providers and have started a nationwide audit of psychotherapy services. As part of our body of work related to psychotherapy, we are considering analyzing Medicare claims data to determine whether Medicare payment	FY 2022

	Services Provided via Telehealth During the Public Health Emergency	amounts for mental health services have decreased over the years. If so, we will also analyze whether this reduction in Medicare payment amounts has resulted in a decrease in the mental health providers that accept Medicare, which may impact beneficiary access to care.	
2	Audit of SAMHSA's Certified Community Behavioral Health Clinic Expansion Grants	Certified community behavioral health clinics (CCBHCs) are designed to provide comprehensive 24/7 access to: (1) community-based mental health and substance use disorder services, (2) treatment of co-occurring disorders, and (3) physical health care in one location. For FY 2020, SAMHSA awarded 179 expansion grants to CCBHCs located in 32 States, totaling approximately \$450 million through the Coronavirus Aid, Relief, and Economic Security (CARES) Act. We will determine whether SAMHSA followed its policies and procedures for awarding and monitoring CCBHC expansion grants. Subsequently, we will conduct additional audit to determine whether CCBHCs used expansion grant funds in accordance with Federal requirements and applicable grant terms.	FY 2023
3	Projects for Assistance in Transition from Homelessness Program	HHS provides Federal funds to various States to administer the PATH program. The PATH program supports the delivery of outreach and various services to individuals with serious mental illness and those with co-occurring substance use disorders who are experiencing homelessness or are at imminent risk of becoming homeless. We will determine whether grant recipients complied with Federal requirements in providing PATH program services.	FY 2022
4	Post-Award State or Tribal Audits of Substance Abuse and Mental Health Services Administration's Opioid Response Grants	SAMHSA has awarded a series of grants to combat opioid use disorder. The purpose of these grants is to increase access to treatment, reduce unmet treatment need, and reduce opioid overdose related deaths. The audit will determine how select States or Tribal agencies implemented programs under these grants and whether the activities complied with Federal regulations and met program goals.	FY 2022
5	Audit of States' Administration of SAMHSA's Substance Abuse Prevention and Treatment Block Grant Funding	SAMHSA's Substance Abuse Prevention and Treatment Block Grant (SABG) program is the largest Federal program dedicated to improving publicly funded substance abuse prevention and treatment systems. The program provides funds to all 50 States, the District of Columbia, and U.S. Territories to prevent and treat substance abuse. Federal requirements for the SABG program state that fiscal control and accounting procedures must permit the tracing of funds to a level of expenditure adequate to establish that such funds were not used in violation of block-grant restrictions and statutory prohibitions (45 CFR § 96.30). We will determine whether the States' SABG expenditures for subrecipients, including expenditures for contracted transitional housing providers, complied with Federal and State requirements.	FY 2022

6	Audit of Medicaid Applied Behavior Analysis for Children Diagnosed with Autism	<p>Autism spectrum disorder (autism) is a developmental disability that can cause significant social, communication, and behavioral challenges for children. A common treatment for autism is Applied Behavior Analysis (ABA), which can help an autistic child improve social interaction, learn new skills, maintain positive behaviors, and minimize negative behaviors. We will audit Medicaid claims for ABA services provided to children diagnosed with autism to determine whether a State Medicaid agency's ABA payments complied with Federal and State requirements.</p>	FY 2022
7	Utilization of Medication-Assisted Treatment in Medicare	<p>The opioid crisis remains a public health emergency. The current COVID-19 pandemic makes the need to focus on the opioid crisis even more pressing. Recent HHS-OIG studies have found that the utilization of drugs for MAT is low and that concerns exist related to access. This study will assess the extent to which Medicare beneficiaries with opioid use disorder are receiving MAT drugs through Medicare and the extent to which they are receiving counseling or behavioral therapies. It will also determine whether Medicare beneficiaries with opioid use disorder who are not receiving MAT drugs have certain characteristics in common.</p>	FY 2022

APPENDIX 2: HHS-OIG Telehealth Reviews

HHS-OIG’s Recently Published Reports on Telehealth

The following table contains a description of HHS-OIG’s recently published reports related to telehealth access. We would be happy to provide information on other work if requested.

	Title of Review	Description	Issued
1	Opportunities Exist To Strengthen Evaluation and Oversight of Telehealth for Behavioral Health in Medicaid	<p>This data brief provides insight into State evaluations and oversight of telehealth for behavioral health services as of January and February 2020, before the expansion of telehealth due to the COVID-19 pandemic. It provides a useful foundation to inform CMS and State decisions about how to evaluate the impacts of telehealth on access, cost, and quality of behavioral health services and to strengthen oversight of program integrity. Evaluating the effects of telehealth on access, cost, and quality is particularly important in helping States make decisions about how to best use telehealth and about which populations benefit most from these services. Understanding States’ efforts to oversee telehealth can help States protect their Medicaid programs. Further, States’ expansion of telehealth during the COVID-19 pandemic has been largely on a temporary basis. As States consider making telehealth expansions permanent, States can use information in this data brief to help determine which services best support enrollees. This data brief is a companion report to a data brief that describes the challenges States reported with using telehealth to provide behavioral health services to Medicaid enrollees.</p>	September 2021
2	States Reported Multiple Challenges With Using Telehealth To Provide Behavioral Health Services to Medicaid Enrollees	<p>This data brief provides insight into States’ challenges as reported in January and February 2020, before the expansion of telehealth due to the COVID-19 pandemic. It provides a useful foundation for CMS and States by highlighting longstanding challenges with the use of telehealth that existed prior to the additional challenges caused by the pandemic. Understanding States’ challenges with using telehealth to provide behavioral health services can help States improve their Medicaid program and assist enrollees with accessing needed care. Further, States’ expansion of telehealth during the COVID-19 pandemic has been largely on a temporary basis. As States consider making telehealth expansions permanent, they can use information in this data brief to develop effective programs and troubleshoot challenges in implementation. This data brief is a companion report to a data brief that describes the extent to which States evaluate the effects of telehealth on access, cost, and quality of behavioral health services and the extent to which States oversee telehealth for fraud, waste, and abuse.</p>	September 2021

3	Provider Shortages and Limited Availability of Behavioral Health Services in New Mexico's Medicaid Managed Care	<p>Shortages of providers and difficulty arranging services has resulted in limited availability of behavioral health care for New Mexico's Medicaid managed care enrollees. The challenges faced by New Mexico are likely shared by other States and require both State and national attention. Both CMS and New Mexico agreed with HHS-OIG's recommendations to help address these challenges, including expanding the behavioral health workforce, improving transportation options for enrollees, and expanding the use of telehealth.</p>	September 2019
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HHS-OIG's Ongoing Work

The following table contains the full description of HHS-OIG's ongoing telehealth audits and evaluations.

	Title of Review	Description	Expected Issuance
1	Data Snapshot: Review of Beneficiaries Relationships With Providers for Telehealth Services	<p>In response to the COVID-19 pandemic, both Congress and HHS expanded access to telehealth for a wide range of services. This expansion enhanced the ability of health care providers to offer care to Medicare beneficiaries remotely during the COVID-19 pandemic. During the expansion, HHS used its enforcement discretion to relax the requirement that a beneficiary must have an established relationship with a provider to receive certain telehealth services. This data snapshot will describe the extent to which Medicare beneficiaries had established relationships with providers from whom they received telehealth services. We will also look for any differences in these relationships between traditional Medicare and Medicare Advantage and among the different types of telehealth services.</p>	FY 2022
2	Audit of Home Health Services Provided as Telehealth During the COVID-19 Public Health Emergency	<p>On March 13, 2020, President Trump declared a national emergency in response to the COVID-19 pandemic, which allowed CMS to take proactive steps to support the response to COVID-19 through the use of section 1135 waivers. By means of this authority, CMS waived certain requirements to expand Medicare telehealth benefits to health care professionals who were previously ineligible, including physical therapists, occupational therapists, speech language pathologists, and others. However, the waiver does not allow for payment of telehealth services on home health claims. In the COVID-19 Public Health Emergency Interim Final Rule With Comment, CMS amended regulations on an interim basis to allow home health agencies to use telecommunications systems in conjunction with in-person visits. In the CY 2021 Home Health Prospective Payment System Final Rule, CMS permanently finalized these changes. The final amended regulations state that the plan of care must include any provision of remote patient monitoring or other services furnished via telecommunications technology or audio-only technology, and that such services must be tied to patient-specific needs as identified in the comprehensive assessment. The regulations further state that telehealth services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment. We will evaluate home</p>	FY 2022

		health services provided by agencies during the COVID-19 public health emergency to determine which types of skilled services were furnished via telehealth, and whether those services were administered and billed in accordance with Medicare requirements. We will report as overpayments any services that were improperly billed. We will make appropriate recommendations to CMS based on the results of our review.	
3	Audits of Medicare Part B Telehealth Services During the COVID-19 Public Health Emergency	Telehealth is playing an important role during the public health emergency, and CMS is exploring how telehealth services can be expanded beyond the public health emergency to provide care for Medicare beneficiaries. Because of telehealth's changing role, we will conduct a series of audits of Medicare Part B telehealth services in two phases. Phase one audits will focus on making an early assessment of whether services such as evaluation and management, opioid use order, end-stage renal disease, and psychotherapy (Work Plan number W-00-21-35801) meet Medicare requirements. Phase two audits will include additional audits of Medicare Part B telehealth services related to distant and originating site locations, virtual check-in services, electronic visits, remote patient monitoring, use of telehealth technology, and annual wellness visits to determine whether Medicare requirements are met.	FY 2022
4	Home Health Agencies' Challenges and Strategies in Responding to the COVID-19 Pandemic	Home health agencies (HHAs) have faced unprecedented challenges to providing care during the COVID-19 pandemic. Reported challenges include, but are not limited to, procuring necessary equipment and supplies, implementing telehealth to treat patients remotely, and addressing staffing shortages. However, the full spectrum of these challenges, including how challenges have evolved over time, is unknown. HHAs have used strategies to address these challenges, but the array of strategies and the extent to which HHAs found them helpful are also unknown. This nationwide study will provide insights into the strategies HHAs have used to address the challenges presented by COVID-19, including how well their emergency preparedness plans served them during the COVID-19 pandemic.	FY 2022
5	Medicare Telehealth Services During the COVID-19 Pandemic: Program Integrity Risks	In response to the COVID-19 pandemic, CMS implemented a number of waivers and flexibilities that allowed Medicare beneficiaries to access a wider range of telehealth services without having to travel to a health care facility. This review will be based on Medicare Parts B and C data and will identify program integrity risks associated with Medicare telehealth services during the pandemic. We will analyze providers' billing patterns for telehealth services. We will also describe key characteristics of providers that may pose a program integrity risk to the Medicare program.	FY 2022
6	Use of Medicare Telehealth Services During the COVID-19 Pandemic	In response to the COVID-19 pandemic, CMS made a number of changes that allowed Medicare beneficiaries to access a wider range of telehealth services without having to travel to a health care facility. CMS proposes to make some of these changes permanent. This review will be based on Medicare Parts B and C data and will look at the use of telehealth services in Medicare during the COVID-19 pandemic. It will look at the extent to which telehealth services are	FY 2022

		being used by Medicare beneficiaries, how the use of these services compares to the use of the same services delivered in person, and the different types of providers and beneficiaries using telehealth services.	
7	Medicaid— Telehealth Expansion During COVID-19 Emergency	As a result of the COVID-19 pandemic, State Medicaid programs have expanded options for telehealth services. Rapid expansion of telehealth may pose challenges for State agencies and providers, including State oversight of these services. Our objective is to determine whether State agencies and providers complied with Federal and State requirements for telehealth services under the national emergency declaration, and whether the States gave providers adequate guidance on telehealth requirements.	FY 2022