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Good morning, HCCA compliance community, and happy Monday. And if you're on the West Coast, thank you for waking up a little earlier today. I am honored to kick off the 25<sup>th</sup> Annual Compliance Institute. 25 years! On behalf of HHS-OIG, congratulations to HCCA on that impressive milestone and for building an enduring community of compliance professionals, attorneys, auditors, and others. HCCA is an invaluable partner; we share a mission to improve the efficiency and effectiveness of the health care system by better ensuring health care rules are understood and followed. Our shared mission positively impacts patients, providers, and health care programs. Because of HCCA and this community, compliance is not just another requirement to be met. Instead, compliance is a core value of health care organizations across the country. That culture of compliance leads to improvements for patient safety, quality of care, and provider operations, and protects billions in health care dollars by mitigating fraud, waste, and abuse. OIG looks forward to continuing this mission with all of you and increasing our impact over the next 25 years and beyond.

Last April, when we gathered virtually for the 24th Compliance Institute, we were just beginning to realize the magnitude of the COVID-19 pandemic. And we were beginning to understand the many difficulties that lay ahead. Unfortunately, a year later, we know those difficulties are far from being over. We will long remember this period of time. Most somberly, we will remember those who lost their lives to COVID-19: to date the 3.01 million people globally and 563,980 people living in the U.S.

Over this past year, we have seen the incredible and oftentimes heroic efforts of the health care industry as it responded to the pandemic. Across the health care system, we have witnessed remarkable heroism from clinicians, support staff, and other essential workers. These efforts include many of you and your work alongside health care professionals caring for the sick and researchers developing effective treatments and vaccines.

Today, with over 84.3 million individuals living in the U.S. being fully vaccinated and nearly 3.5 million more being vaccinated each day, we see astonishing progress, made possible with the collective effort of the health care industry, government, research institutions, and many others.

Yet we all recognize there is still much to be done, studied, and remedied going forward. And we also see that the heroism of many has come at a great cost. More than 3,600 U.S. health care workers have lost their lives due to COVID. OIG knows that many health care organizations, professionals, and others are stretched thin due to the ongoing challenges in responding to COVID-19.

At the end of February of this year, we surveyed hospital administrators at 320 randomly selected hospitals across the country. We wanted to understand the challenges in responding to the pandemic and what was needed going forward. One goal of this work was to make sure that policymakers and stakeholders had a snapshot of these issues roughly a year into the response. We learned from this survey that COVID is still exerting significant strain on hospitals nationwide and hampering their ability to care for patients, staff, and communities. Hospital administrators described how they have been operating in “survival mode” for an extended time, grappling with new problems that arrived with the pandemic, and seeing the exacerbation of longstanding issues. We heard about four core challenges: (1) balancing providing health care for complex, resource-intensive COVID patients with efforts to resume routine care for their communities; (2) staffing challenges related to burnout and competition for workers; (3) vaccination efforts that were positive steps towards recovery, but pose staffing, logistical, and patient access challenges, and (4) the strain on hospital finances. We need to learn from these challenges because, as the CDC Director says, we are likely to see another worldwide pandemic well before another 100 years.

We appreciate the many hospital administrators, likely including some of you, who talked to us about COVID challenges and how to address them. Hospitals identified areas for further government support, such as updated guidance about quarantine procedures for the vaccinated, emerging variants, use of COVID relief funds, and possible changes to telehealth. The report has been widely shared with agencies in the Federal Government working on the pandemic response and with Congress and is available on our webpage.

For OIG's part, as we conduct our work during the pandemic, we will continue to consider the unique context in which industry is presently operating. And to act fairly and communicate regularly with the goal of getting good information to the industry and to our stakeholders. We continue to plan and conduct work with an eye toward potential burdens on providers and the safety of the health care workforce, patients, and OIG's staff. We assess compliance based on the requirements and policies put in place by Congress and the U.S. Department of Health and Human Services during the pandemic, including the public health emergency flexibilities.

You and your colleagues may have questions about the off-ramp when emergency flexibilities expire after the pandemic ends. While we don't know exactly when this will be, we commit to taking a reasonable and fair approach to ensure providers can adjust as flexibilities end. Amid the uncertainty of the public health emergency, we recognize that the industry and compliance professionals must keep sight of the broader compliance landscape and try to plan for the future. Clearly communicating today about our broader oversight priorities is one way I can provide predictability so that you can plan for what's next.

In that spirit, this morning I'd like to share OIG's 10 key compliance priorities of particular relevance to this audience. Those ten priorities for this year and beyond are: Overseeing COVID-19 Relief and Response, Realizing the Potential of Telehealth, Ensuring Quality of Care and Patient Safety in Nursing Homes, Advancing Health Equities, Modernizing Program Integrity and Compliance Information, Combatting the Substance Use Disorder Epidemic, Prioritizing Cybersecurity, Enforcing Information Blocking, Implementing Value-Based Care, and Strengthening Managed Care Program Integrity.

This list is, of course, not our full work plan. We are responsible for overseeing HHS's \$2.2 trillion in program expenditures made in fiscal year 2020, and our work spans the over 100 programs at the Department of Health and Human Services. We are continuing substantial work in core areas, such as Medicaid program integrity, prescription drug fraud, quality of care provided through the Indian Health Service, the unaccompanied children's program managed out the Office of Refugee Resettlement, grants and contracts fraud, research protections and combatting improper foreign influence in research, and many, many others.

We update our public work plan monthly to maximize transparency about our work.

The 10 key priorities you saw on the last slide are culled from our broad portfolio because they are of particular relevance to compliance professionals and would benefit from enhanced focus. They are topics about which we believe focus on compliance, fraud prevention, and program effectiveness can make a real difference for program efficiency and for the health and wellness of people served by HHS programs. Together, these 10 areas will drive much of OIG's work in the coming year and beyond, and I would submit that they should be toward the top of the agenda for the compliance community as well.

It would take more time than we have this morning to go through all of the 10, so I'll focus on 5: COVID-19, Telehealth, Nursing Homes, Health Equities, and Modernizing Program Integrity Information.

I'll cover why each is a priority for OIG, provide relevant updates, and a brief look at what's ahead. For more information, there is a handout included with the presentation materials that provides detail for all 10 compliance priorities.

First, Overseeing COVID-19 Relief and Response. Audits, evaluations, and investigations examining the COVID response will remain a priority for us for several years to come. During this pandemic we have seen the best and worst of human nature. In the best column—health care workers acting heroically, scientists generating life-saving vaccines, communities pulling together to help. But in the worst column—unfortunately, but not unexpectedly because we have seen this in other disasters—we also see bad actors exploiting the pandemic to cause harm.

Since the onset of the pandemic, we have received over 2,400 complaints to our hotline related to purported COVID fraud, some of which have already resulted in enforcement action. For example, about 10 days ago, a Colorado physician was indicted on criminal charges for allegedly stealing from the Accelerated and Advance Payment Program, the Provider Relief Fund, and the Paycheck Protection Program to pay for personal travel and home improvements.

Combatting fraud and abuse in the COVID response requires a whole of Government approach. Law enforcement and oversight agencies across Federal, State, and local governments are responding quickly and aggressively to mitigate schemes that jeopardize public health efforts and the health and safety of people. We are collaborating with these partners on many of the COVID programs to understand the risks and identify controls that may be ineffective at detecting fraud schemes. We are using every tool in our arsenal, pursuing criminal or civil charges, seeking exclusion or referring for suspension and debarment from programs, and working to recover ill-gotten gains.

Aggressively pursuing criminals is just part of our enforcement toolkit. We also prioritize informing the public about ongoing COVID fraud schemes so that individuals and organizations can take steps to protect themselves. For example, we issued a notice about vaccine fraud scams that utilize disposed vaccine materials to commit fraud. I encourage your organizations to be mindful when disposing of COVID-19 materials such as syringes, vials, vial container boxes, vaccination record cards, and shipment or tracking records so they do not fall into the wrong hands. And just last week, we sent a message regarding compliance issues related to the CDC Vaccine Program based on patients' complaints regarding charges by providers when getting their COVID-19 vaccine. For more information on that topic, and other COVID and vaccine fraud alerts, please see OIG'S COVID-19 portal on our website.

The size of the pandemic relief dollars that Congress has provided is massive. Since 2020, Congress has passed more than \$5 trillion in COVID-19 related relief spending. For context, \$5 trillion is more than all Federal spending in 2019. OIG's oversight will cover the \$463 billion in COVID funding provided to or flowing through HHS.

This enormous level of spending requires oversight to ensure it is used for intended purposes. Much of that will be done by other Inspectors General and in coordination with the Pandemic Response Accountability Committee, or PRAC. PRAC is composed of Federal Inspectors General—including us. PRAC has a mandate to focus on mitigating risks that cut across program and agency boundaries. For the next 4 years, PRAC's mission is to promote transparency and to conduct, coordinate, and support oversight of COVID-related funds and the pandemic response. PRAC's work should be on your radar. Its work can help you

understand how the large amount of COVID-relief funding affects your organization and how that may lead to downstream compliance issues.

At HHS-OIG, we are currently conducting 57 audits and evaluations related to COVID-19. And to date, we've issued eight reports, including the recent Hospital Survey. Our oversight covers a range of COVID issues, including audits of the Provider Relief Fund and the related Uninsured Program Fund. These new programs with billions in funding were established rapidly to aid the health care industry through the COVID response. Given that these funds will have a limited period of availability, reviewing these programs early will lead to better transparency and accountability to ensure the programs have appropriate safeguards. You can find a complete listing of our COVID work, our full COVID-19 strategic plan, and other information through the COVID-19 portal on our website.

Our goals with COVID work are twofold: to understand how pandemic relief funds were spent and services delivered and to understand how to improve capacity for the next pandemic, infectious disease outbreak, or other catastrophic event. To this end, while much of our current work focuses on what is happening presently on the ground, future OIG work will look retrospectively to understand how events unfolded, glean lessons learned and best practices, and make recommendations for improvements to planning, preparedness and response.

The second compliance priority is Realizing the Potential of Telehealth. There is a lot of interest from our stakeholders, the health care industry, and others about lessons learned from the pandemic in providing virtual care. Telehealth may be the prime example. Many are considering how to expand coverage for telehealth based on the experience providers and patients had during the pandemic. Even though our work examining telehealth is not yet complete, there are many discussions happening now about the future of telehealth and we want to ensure program integrity is appropriately considered. As part of OIG's mission to provide objective and independent information, last month we issued a message regarding telehealth based on what we know at this point in time.

We recognize the potential of expanding options for accessing health care services through telehealth and other technologies like remote patient monitoring, on improving care coordination and health outcomes. It is important

that new policies and technologies with potential to improve care and enhance convenience achieve these goals and are not compromised by fraud, abuse, or misuse.

Effectively expanding telehealth and ensuring program integrity will take effort on a number of fronts that may not be considered traditional compliance issues: cybersecurity, interoperability, and patient access to technology. All key elements that compliance professionals can help support as organizations adopt and refine their use of telehealth. For example, if deployed carefully and with patients at front of mind, telehealth can be a tool for providers to help address patient access issues, especially for underserved populations. Prior OIG work has identified telehealth as a tool to improve access to behavioral health care for Medicaid beneficiaries. And OIG's significant body of ongoing telehealth work will touch on many of these issues and provide more information to stakeholders to help ensure the potential benefits of telehealth are realized for patients, providers, and HHS programs, while identifying key program integrity factors as policy and payments changes are considered.

Third is Ensuring the Quality of Care and Patient Safety in Nursing Homes. The cruel reality of COVID has underscored just how vulnerable patients are in nursing homes and other long-term care facilities. Residents in these facilities account for less than 1 percent of the nation's population but make up 34 percent of the COVID-19 deaths.

Our work examining nursing homes touches on many problems that pre-date and have now been exacerbated by the pandemic. This includes a recent report on nursing home staffing levels and problems with how those data are reported by facilities. And as COVID required nursing facilities to isolate their patients and close facilities to families, friends, and others, we conducted an outreach campaign aimed at protecting nursing home residents at 493 nursing homes. Our agents and State partners provided education materials about how staff and patients should report complaints related to unsafe COVID-19 practices, abuse and neglect, other quality concerns, and fraud.

Our work related to nursing facilities will continue to focus on quality of care, patient safety, and improving CMS and state oversight because OIG recognizes much is left to be done. We hope the work will shed light on infection control and

nursing facility-initiated discharges of patients and will build on our body of work examining use of psychotropic drugs in these facilities.

It is so important that we work together to make progress on these critical issues. The problems in nursing facilities are not just for nursing home residents, workers, and staff. If you work at a hospital or other type of provider, nursing facilities are integral to the health of the entire system. Better, safer nursing homes mean fewer hospital readmissions. And as we learned from our hospital survey, availability of nursing home beds directly impacts hospital discharge planning. But on a more human level, I think many people have struggled with the decision to place a loved one in a nursing home. They are rightfully concerned with safety and quality of life at these facilities across the country. And OIG's long history of work backs that up.

That has to change. The toll that COVID-19 took on nursing home residents underscores that need. At OIG we are going to be laser focused on seeing positive change in the nursing home space.

The fourth priority is Advancing Health Equities. Just as COVID highlighted long-standing issues related to nursing facilities, it also demonstrated how stark racial and socioeconomic disparities in our country have significant negative effects for health outcomes. As of March 2021, CDC data show that American Indian or Alaska Native individuals are 2.4 times more likely to die from COVID-19 than white Americans. For Hispanic or Latino Americans, the rate is 2.3 times more likely, and for Black Americans the rate is 1.9 times. It is clear this pandemic has disproportionately affected communities of color—worsening the impact of disparities related to the social determinants of health.

OIG oversees many health and human services programs meant to reach underserved populations, improve access to health and human services programs, and address disparities in care and outcomes. As Government and the private sector grapple with systemic equity problems, I want to share what we are doing to ensure that our oversight can help address these issues. First and foremost, we are bringing equity to the forefront of our work planning by considering how our work can incorporate objectives related to equity, social determinants of health, and their effects on health experiences and outcomes.

We also have new work underway specifically examining disparities. We are interested in questions like whether funding is distributed to account for potential health disparities; whether demographics data are complete and accurate; and how such data are used to address inequities. We also want to infuse our work with an equity lens to ensure that we are identifying where HHS programs can potentially do better to achieve health equity in areas like quality of care, access to care, and health outcomes.

And like many of you, we are also turning an inward lens to ensure that our own organizational culture fully embraces diversity, equity, and inclusion in action as well as word.

Finally, our newest compliance priority, and one I am particularly excited about: Modernizing Program Integrity and Compliance Information.

We have been thinking about what OIG can do to make program integrity and compliance easier across the health care industry. We all know that when we make something easier to accomplish, we often get more of that thing.

Modernizing program integrity and compliance information means making it easier for you to access and use information that supports your work. Through doing so, we hope to spur innovation and improve compliance programs.

During the pandemic, we all had to find new ways to work. In response, I'm sure you found new approaches to implement and carry out compliance functions, advise your clients, run your offices, and work with your colleagues. Similarly, OIG had to find new ways to carry out our mission.

Over the past year, we did a few things differently. For example, to provide expedited guidance during the pandemic, we took and are taking questions from the public about the application of the anti-kickback statute to pandemic-related business arrangements and posting frequently asked questions or FAQs in response. And we worked with organizations that needed extensions of deadlines by providing flexibilities for 42 self-disclosure actions, 81 Corporate Integrity Agreements, and 20 payment extensions in our civil monetary penalty cases. While not all of these practices will continue after the public health emergency, we are assessing what worked well and what to keep after the pandemic.

This new initiative will learn from those efforts. To do so, we need to hear from you. We will be seeking feedback in the near future from health care industry stakeholders about how to modernize the types of program integrity and compliance information OIG provides. This includes the various guidance and other resources OIG has published over the last several decades, such as advisory opinions, Special Advisory Bulletins, Special Fraud Alerts, compliance program guidance documents, and the COVID-19 FAQs. Your feedback in this area will be critical as we make plans for future guidance that we intend to make as useful and meaningful as possible for you and your organizations.

We're also exploring a number of ways to improve how program integrity and compliance information is provided to the health care industry and others. This effort will start with us. For example, the List of Excluded Individuals and Entities or LEIE gets 26 million visits annually, and we recognize that using it often requires a manual process. As part of this new initiative, we are considering how best to adopt modern data sharing practices for the LEIE, such as application programming interfaces, also known as APIs. Modernized LEIE information will mean that data are easier to access through compliance software and apps that use APIs, and can support the development of new tools and approaches to compliance.

As we learn from this initiative, we will expand our work to improve how you can access and use program integrity and compliance information. That may include a range of efforts from the use of modern data techniques, to publishing data toolkits, or hosting virtual compliance roundtables. Ultimately, this initiative is about making information more useable for you, the health care industry, and our program integrity partners.

That is why this initiative will be based on the insights from health care compliance professionals. We want to better understand your program integrity and compliance information needs, what modernization efforts your organizations have ongoing, and how we can work together toward modernizing program integrity and compliance information. This will not happen overnight. We anticipate a multi-year effort. You'll be hearing more from OIG on this initiative later this year.

Bringing our time together to a close. To have a positive impact on improving program integrity in the 10 Key Compliance Areas, OIG will leverage all of our enforcement, oversight, and compliance tools. Through enforcement, we will continue to investigate allegations of improper conduct and work with our Federal and State law enforcement partners to hold wrongdoers accountable. When it comes to oversight and compliance, our aim is to provide timely, actionable information to the Department, our Government partners including at PRAC, health care providers, and others to improve the detection and prevention of fraud, waste, and abuse.

We recognize that oversight and compliance is a team effort. We don't run programs or deliver health care services. We provide independent and objective findings, make recommendations, and issue industry guidance. It is then up to the Department, States, and health care providers to take that information and turn it into real improvements for patients, programs, and the health care system. It is a business imperative then that we work with and understand the perspectives of the programs and health care providers to increase our impact. This is one reason our decades-long partnership with HCCA is invaluable. In this forum we come together to figure out how we can best pursue our shared compliance goals, learn from one another, and amplify the importance of compliance in the health care system.

You can get more details and insights on all of OIG's work throughout the rest of the Compliance Institute from the 14 different OIG presenters. They will cover the latest OIG information about a range of issues including: compliance risk assessments, exclusions, electronic health record regulatory risks, how best to work with an Independent Review Organization, and more. In addition, OIG's panel of five Deputy Inspectors General will discuss current developments for each of OIG's core components. Thank you again to HCCA for inviting me to kick off the 25th Annual Compliance Institute. I wish you a very successful conference. On behalf of OIG, we look forward to our continued partnership to foster the very highest standards of health care compliance.