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Good morning. I am happy to be joining this very important AHLA fraud and compliance forum virtually and want to acknowledge how fortunate it is that we're still able to connect during an unprecedented and challenging time. Thank you to all the planners at AHLA who have made this possible and for the invitation to address you today. Much of my talk focuses on interconnectivity and what OIG has been up to using data, technology, and innovative methods and partnerships so we can carry out our important mission. It's not lost on me that it is technology and innovative thought and flexibility that is making my communication with AHLA members today possible. I am delighted that some of our top attorneys and law enforcement officials are also presenting at this Forum.

On behalf of OIG, I want to recognize the incredible efforts of the health care industry to respond to the pandemic. Across the health care system, we have witnessed extraordinary heroism from clinicians, support staff, and other essential workers.

They are heroes among us—that cannot be said enough.

I also want to recognize those behind the scenes working to support the industry's efforts to care for the sick and to find effective treatments and vaccines. This includes the lawyers, compliance professionals, and executives who are guiding hospitals, physician practices, and others through uncharted waters and fast changing regulatory landscapes.

It is essential to meet people where they are at during an emergency—and today I'll talk about what we've been doing to meet the health care industry where it's at.

We are here, virtually, to consider fraud and compliance in health care and the laws and tools available to ensure that payments are accurate and that patients receive quality care. These familiar goals take on new urgency as massive resources are being marshalled by Government and the private sector to respond to the pandemic and sustain vital health care services. The challenges in responding to the pandemic are many, thorny, and unprecedented. Consequential decisions must be made moment-by-moment. Oversight, transparency, program integrity, and accountability then have never been more important.

I am proud to say that during the pandemic, OIG has not missed a beat. And, really, given what is at stake, we could not and will not. We simply cannot. Our mission is too vital, particularly when health, safety, and massive taxpayer investments are on the line. Over the past few months and likely many months into the future, COVID takes center stage.

To work effectively in this arena—at any time, but perhaps especially at this time—it helps to have a broad perspective and appreciation for the complexity of our health care system and its rules. I have been involved in oversight of HHS programs for over 20 years. I actually got my start at the Health Care Finance Administration—now the Centers for Medicare & Medicaid Services—where I audited contractors across the country. Later, as a policy and program analyst at OIG, I studied the impact of prospective payment policies in Medicare, quality of care in hospitals, and the Medicare appeals process, among many other topics. As an OIG executive for a decade, I had the opportunity to delve deeply into matters of enforcement, compliance, fraud detection, and auditing. And since January, it has been my great honor to lead OIG.

OIG is the biggest civilian Federal OIG.

Our oversight responsibility extends to every HHS program, including CDC, NIH, FDA, and of course, CMS. All told, HHS, with a budget of about \$1.3 trillion, makes up about one-third of the Federal budget. Our oversight responsibility of HHS is vast. Based on our appropriated funding, about 80 percent of OIG's work focuses on Medicare and Medicaid, and about 20 percent on all other HHS programs. Historically, our total budget is about .03 percent of HHS's budget. That would be like asking the city government of Houston to oversee the entire European Union (pre-Brexit). Together with our partners at DOJ and HHS, we return about \$4 for every dollar we spend. That number only represents some of our impact. Some work protects patients or recommends program improvements, even if it doesn't return money to the Treasury. We are a terrific investment.

To get big results with, comparatively, not a lot of resources, we need to be both effective and efficient. So we are using interconnectivity in all its forms to optimize our impact. We harness data and technology to do the job. We cultivate public and private partnerships because we know fraudsters do not respect silos; a Medicare fraud scheme is likely also affecting Medicaid and private insurance. And in many cases, those same actors are likely exploiting Federal grants and contracts. If an HHS grant program is being ripped off, chances are the same bad actors are stealing from other agencies' programs.

Our teams tackle the knottiest problems by connecting the perspectives of multiple experts, whether it's agents, attorneys, auditors, data scientists, clinicians, or other specialists. Faced with complexity, experience teaches that many lenses are better than one. None of us can do it alone. The more dots we connect, the more patterns we detect, the sturdier networks we build, the better we are as guardians against fraud, waste, and abuse and as partners to those, in and out of Government, who are working to root out fraud and improve health care delivery. Truly, we are all in it together.

So, let's dive in to what OIG is up to. The remainder of my remarks will address OIG's pandemic-related work and our additional oversight and enforcement priorities. And then I'll wrap up with my reflections on what I've learned about leading during a crisis.

Much of OIG's focus at this time is, appropriately, COVID-related. From audits and evaluations that are posted on our public website, to legal guidance providing flexibility to the industry during this challenging time, to enforcement actions—COVID is taking centerstage for HHS-OIG. Our general strategy for oversight is to focus on four goals: protecting people, protecting funds, protecting

infrastructure, and promoting effectiveness now and into the future. I want to spend a little time here on protecting people and funds, where the bulk of our work is now.

**Protecting people.** An essential HHS responsibility during COVID is to protect the health and safety of people, and we are providing oversight to help ensure that HHS efforts to protect people are effective. We are combating fraud schemes that endanger people and issuing public information and guidance about fraud and abuse.

Our announced work includes reviews of health and safety at nursing homes, hospitals, and dialysis facilities. Reviews of CDC's production and distribution of COVID-19 lab test kits and several aspects of the supply chain. We also have two important reviews of program effectiveness related to health care disparities. As Dr. Fauci and others have observed, the pandemic has exposed health care disparities that are deeply troubling.

And we are vigilantly combating fraud schemes that offer fake treatments, bogus contact tracing services, and nonexistent vaccines to vulnerable populations. Unfortunately, we know from past experience that greedy perpetrators exploit fear and confusion to steal during emergencies. Sadly, this pandemic has been no different. Some fraudsters are adapting existing fraud schemes, while others devise new ones. Fraudsters target beneficiaries through telemarketing calls, text messages, social media platforms, and door-to-door visits to gain access to personal information. They steal identities from beneficiaries and money from taxpayers.

It is appalling, and we are working with partners across all levels of government, to stop COVID-related fraud and to bring perpetrators to justice.

**Protecting funds.** Congress recognized that the pandemic response would be a multi-agency, multi-program, and multi-dimensional effort. Thus far, under the CARES Act and related legislation, Congress has made \$2.6 trillion specifically available for response and recovery. The big buckets of aid are for individuals; small businesses; big companies; health—and that includes hospitals, physicians, and public health; Federal safety net; State and local governments; and education. This map shows the current distribution of funds by county with darker colors meaning more money. \$2.6 trillion is hard to wrap your brain around. To provide some perspective, one would need to spend \$1 million a day for 7,123 years to spend \$2.6 trillion. COVID funding is spread across 39 Federal agencies and as of earlier this month had been distributed to 3.9 million recipients.

To date, HHS has been appropriated just over \$251 billion for COVID response and recovery. The biggest bucket of new funding, \$175 billion, is for the Provider Relief Fund.

Provider Relief funds are awarded to provide financial relief for providers and to pay for testing and treatment for COVID-19 for uninsured patients. As you see here, HHS is distributing the funds in several waves. The first two distributions (the two boxes on the bottom left) were made to hospitals, physician groups, and other providers based on Medicare fee-for-service data. Notwithstanding, CMS does not operate this program. The Provider Relief Fund is being run by the Health Resources and Services Administration, which is one of the largest grant-making divisions in HHS. Additional targeted distributions (the bottom right box) are for high-impact areas, rural providers, skilled nursing facilities and nursing homes, Tribal facilities, and safety net hospitals.

Many of your clients and organizations may receive this funding. So here's what you need to know about OIG's role:

OIG will have a big role to play in providing oversight for these funds. For example, we are auditing HHS's controls over the award and distribution of funds and determining whether payments were correctly calculated and distributed to eligible providers. We will also be determining whether providers that received PRF payments complied with the terms and conditions for reporting and expending PRF funds. We are connecting a wide range of data sources and monitoring for potential fraud, including falsified attestations or submissions to the Government by providers claiming or retaining funds. We will have many watchful eyes on the PRF.

Switching to protecting funds in the Medicare and Medicaid space, we are looking at Medicare claims for add-on laboratory tests that piggyback on COVID-19 testing. We are conducting work looking at the use and potential program integrity risks associated with expanded Medicare and Medicaid telehealth waivers during the pandemic. And we've recently announced work looking at whether Medicare payments for COVID-19 inpatient discharges comply with requirements. These are all areas for focus from a compliance perspective. And if we find fraud, we will pursue it through enforcement.

In addition to audits and evaluations, relators are filing False Claims Act cases related to COVID fraud, with allegations involving testing, treatments, and other issues. We will pursue fraud criminally, civilly, and administratively to protect Federal funds and beneficiaries.

Just as importantly, in recognition that providers, particularly frontline caregivers, needed flexibility to meet the demands of responding to the COVID-19 public health emergency, we issued guidance for health care providers on the application of our fraud and abuse statutes. To date, we have issued waivers and FAQs on topics such as cost-sharing for telehealth services to topics on hospitals and independent practices that are renting space or loaning equipment to each other to create surge capacity. You can find this guidance through the COVID-19 portal on our webpage.

In a March statement, OIG pledged to work with organizations that needed extensions of deadlines to produce data or comply with a Corporate Integrity Agreement. And we have done so. To date, we have paused 24 self-disclosure actions, agreed to 70 accommodations (extensions of time and modification of terms) under Corporate Integrity Agreements to providers impacted by COVID-19, and granted 15 payment extensions in our civil monetary penalty cases. We are planning new work and continuing ongoing oversight with an eye towards burden on providers and the safety of the health care workforce, our staff, and patients. With respect to audits, our auditors are aware of flexibilities that have been offered during the public health emergency and take into account the rules in place from the Department when assessing compliance. We strive to be reasonable and fair to providers that are adjusting to rapidly changing program requirements.

All told, we have announced 37 audits and evaluations related to COVID, with more planned. You can find a complete listing of our COVID work, our full strategic plan, and other information through the COVID-19 portal on our website.

Before I move on to non-COVID work, I want to touch on an important element in COVID oversight—the Provider Relief Accountability Committee, or "PRAC."

Congress called for transparency and strong oversight of all Federal COVID funds in the CARES legislation and established PRAC. The PRAC is composed of Federal Inspectors General—including HHS-OIG. For the next 5 years, PRAC has as its mission to promote transparency and to conduct, coordinate, and support oversight of COVID-related funds and the pandemic response. It has a mandate to focus on mitigating risks that cut across program and agency boundaries. Through data and technology, we are better able to see patterns *across* different lines of business. *Across* different programs. And *across* different Departments. This enhanced, multi-lens visibility opens many doors to more targeted, efficient, and effective program operations and oversight. The slide here highlights the 2.0 version of the PRAC website, where you can find data on spending, ongoing work across various Departments, and its 5-year strategic plan.

So that is our COVID portfolio—very important and top of mind. I want to turn to our other, critically important, non-COVID work.

We continue to be focused on objective, independent, relevant, high impact work across HHS programs. We work to prevent and detect fraud, and when necessary, hold wrongdoers accountable. Criminal and civil enforcement remains front of mind, working in tandem with our law enforcement partners. This includes False Claims Act cases, anti-kickback cases, and others. We are continuing our focus on high-impact administrative enforcement with civil monetary penalties and exclusions. Our corporate integrity agreements continue to evolve to meet new risks. You can hear more details about this work from OIG experts over the next 2 days.

For this morning, I want to highlight six emerging areas that we are focused on.

**First:** Managed care. Managed care is a growing area of focus for us from both an enforcement and oversight perspective. Managed care programs are touching more patients and more providers—the managed care program serves approximately 37 percent of the Medicare population, at a cost of about \$264 billion annually. We are rapidly learning that fraud schemes in fee-for-service are being replicated in managed care. Six months after Operation Brace Yourself, a national DME fraud investigation, we saw Medicare fee-for-service claims drop 9 percent, but shortly after, managed care claims for the same type of DME increased 22 percent. Conversely, strategies typical to managed care are also being used in risk-based arrangements in fee-for-service. There is much to be learned about the effectiveness and efficiency of managed care.

As just one example of work in this space, OIG has a significant body of work related to Medicare Part C risk adjustment. Risk adjustment serves an important purpose: pay plans more to provide coverage for beneficiaries who may have more health care conditions, and thus be more expensive to serve. This helps ensure plans don't discriminate against Medicare beneficiaries who may need more services.

Most recently, we issued a report that found \$2.6 billion a year in risk adjustment payments unrelated to any clinical services, but instead were based on diagnoses found in health risk assessments often performed in beneficiary's homes by third-party contractors to the plans. These risk assessments may diagnose a beneficiary with serious conditions such as diabetes with chronic complications. However, none of the services records indicated that the beneficiary was receiving treatment for that condition.

This is a concern because it could signal that beneficiaries are not getting treatment for their medical conditions or plans are using these assessments to fabricate diagnoses. Ensuring that beneficiaries are properly diagnosed is important, not just for the integrity of taxpayer-funded Federal health care

programs, but also for the welfare of the beneficiaries served. Ensuring beneficiaries receive the care they need should be front of mind for plans as they design risk assessment programs with an eye to quality of care and better care coordination.

**Second:** Patient abuse and neglect. OIG has a growing body of work identifying incidents of potential abuse and neglect using data analysis. Over the last couple of years, OIG has released a series of reports using claims data and diagnosis codes to help spot potential incidents of abuse and neglect. Through this work, we have developed promising methodologies that can reliably identify potential incidents of abuse and neglect. Such data analyses can help CMS, States, providers, and others to ensure that no potential abuse or neglect victim falls through the cracks.

Most recently, we examined Medicaid emergency room claims data to identify potential abuse and neglect of children. This data analysis approach identified thousands of children who had an ER claim that were involved with potential incidents of abuse and neglect. And nearly 4,000 of those incidents had not been reported to child protective services.

This type of data analysis is a valuable tool that providers and others can utilize to ensure that all potential abuse and neglect victims are identified and can receive necessary treatment, support, and protection. To facilitate use of this analysis by others, we published “A Resource Guide,” available on our website. I encourage you and your clients to take a look and see if this tool could be useful.

**Third:** Health IT. OIG is increasing oversight of health technology and its effects on fraud, waste, and abuse. For example, earlier this year, the Federal Government settled with Practice Fusion, an EHR company. This was a criminal and civil case where the EHR company partnered with a pharmaceutical manufacturer to design a clinical decision support tool that would promote the opioid products of the manufacturer. This case highlights the need to ensure that the technology that enhances convenience does not compromise integrity.

The same is true for data privacy. Protecting beneficiary data is not just a HIPAA issue. With more data and more entities seeking access to that data, oversight that enhances transparency and accountability about how data are used will be vital.

Interoperability and information blocking are also front of mind as data becomes more fluid and needs to move more freely. ONC and CMS released major rules earlier this year aimed at improving the flow of electronic health information. These rules affect a broad range of entities and have the potential to change the “data dynamics” within the health care sector. As part of this effort, OIG issued a proposed rule that includes information blocking enforcement. An important thing to note is that OIG information blocking enforcement will not begin any sooner than 60 days after we publish the final rule.

The importance of cybersecurity cannot be overstated. The trend toward increased interconnectivity may indeed lead to a more coordinated and connected health care system. And *that* trend will likely increase cybersecurity risk. Cybersecurity is a fraud, waste, and abuse issue. It should not be an issue important only to the provider’s IT team. It also makes sense for attorneys and compliance professionals to have the organizational know-how to help improve health care cybersecurity

Let me tick through the last three issues quickly before I conclude.

**Fourth:** Although hard to predict exactly how, the health care system and Federal programs will likely face many permanent changes as result of the pandemic. We already know that policymakers are considering whether some of the temporary rules should be made permanent, even after the pandemic ends. We are conducting work to better understand many of the rapid changes. Which ones will lead to more economic and efficient programs? Telehealth that is easier for patients and providers? More care delivered at home? Improved nursing home oversight? Bigger incentives to move away from fee-for-service and to value-based care? These are important questions that will shape decisions in coming months and years.

**Fifth:** Coordinated care. OIG continues to work on the Regulatory Sprint to Coordinated Care to facilitate the transformation to value-based care. I can't comment on the specifics of this ongoing rulemaking. But I can say how helpful we found the numerous insightful comments we received from stakeholders. Thank you to anyone here who submitted comments. They really do help our rulemaking process.

**Sixth:** Social determinants of health. Increasingly, policymakers and others are looking at social determinants of health—the conditions where people live, work, and play—as keys to improving health and health outcomes and reducing unnecessary health care spending. The pandemic has brought this to the fore, especially with respect to underserved communities and communities of color. Going forward, this expanded notion of “health” will inform the design of health care programs and, in turn, the oversight at OIG.

All of the issues I hit on today make for a full plate at OIG, and I'm sure many of you are experiencing the same. At OIG, coordination with others and connecting dots across data sources are key ingredients to being efficient and effective. We have a long, fruitful history of coordinating with public and private partners to promote program integrity. From the health care Strike Forces with our Government partners to important collaborations with AHHA, including on seminal guidance for boards of directors. In so many ways, the need for smart, strategic interconnectivity of data and people has never been more important as we look to get results.

I want to close with reflections on what I've learned about serving in OIG's top leadership spot during an unprecedented time.

“People first. Mission next.” When the pandemic hit, OIG needed to pivot its operations from mostly on premises to virtually 100 percent online. The safety and well-being of our staff and the communities in which we live and work needed to come first. But, almost immediately, we were fielding requests about what we would do to ensure our critical mission continued. And that urgency increased as the pandemic spread and HHS distributed funds for testing, treatment, and economic support. We have a great mission at OIG, “protecting HHS programs and the people they serve.” Again and again I have seen the power of a great mission in bringing people to the table to tackle complicated issues. In a tough moment, I have seen the organization inspired and steadied by our mission.

We need to meet people where they are. Of course, auditors knocking on doors of overwhelmed hospitals in hot spots would not be reasonable for the hospitals, patients, or our staff. We had to meet people where they were. We applied that approach to our interactions with the Department and the health care industry, which was suddenly “all-hands-on-deck” and at the frontlines of a new and terrifying virus.

Having a specific strategic plan for COVID work provided direction and common goals for a workforce that was suddenly working in 1,600 home offices, facing massive oversight responsibilities. A strategic plan got everyone rowing in the same direction. But it was also important to be sure our plan was flexible to adapt to changing circumstances. And we are measuring our progress as we go.

Communication, communication, communication. As we manage our workforce remotely, we are battling testing technology and developing chronic video fatigue! Nevertheless, I have found consistent communication—up, down, and across the entire organization to be essential and video has, perhaps, brought me closer than I have ever been to my OIG colleagues across the country. Ensuring we approximate “in-person” communal moments has kept the connection and culture vital and engaged.

I am grateful for the invitation to address you today. I look forward to the day when we can meet safely in person. Thank you, AHLA, for your continued partnership in addressing fraud, waste, and abuse. And Thank you to everyone working to combat this pandemic and take care of patients.