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Remarks as Prepared for Delivery

Good morning to the American Health Law Association (AHLA) community. And if you are watching from the West Coast, thank you for waking up early. Many thanks to AHLA and the Planning Committee for the invitation to speak and for organizing this important forum specifically devoted to health care fraud and compliance.

We continue to live through unprecedented times. Over the past 18 months, we have experienced changes that would have been unimaginable in December 2019. COVID-19 has claimed the lives of 4.6 million people globally and over 656,000 Americans, including more than 3,600 U.S. health care workers. That toll reminds us that we still have much to do, study, and remedy going forward.

We have learned and will continue to learn where significant gaps in our health care system exist. In some cases, these are compulsory lessons about how we can and should do things differently. Lessons that we are likely to carry with us long after the public health emergency ends.

The Office of Inspector General (OIG) has had many discussions about how we can "meet providers where they are at"—to figure out what norms were absolutely essential for this moment, and where some flexibility was needed. We endeavored to get important information into the hands of the provider community as quickly as possible, and we recognized that our guidance and enforcement needed to be nimble and appropriate for the context in which health care providers were operating.

This is what I want to talk about today: meeting the moment in the fight against fraud, waste, and abuse. The history of health care fraud and compliance is a story about how new authorities and approaches have emerged to address the challenges of the time. That history is instructive, and worth a brief review. Then, I will talk about three ways that OIG is meeting the moment we find ourselves in now.

First, I'll cover our new initiative to modernize our guidance and data to make compliance efforts more successful and efficient. Second, I'll touch on our work on a top priority for me: improving nursing home performance. And third, pandemic response oversight.

Turning first to the historical context: A good place to start is with the False Claims Act, arguably the bedrock modern fraud-fighting statute. The False Claims Act was enacted in 1863 during the Civil War. Union troops had a problem. War profiteers were looking to make money off the crisis. Some were selling the Federal Government faulty supplies—mules instead of horses, the same horse multiple times, sawdust instead of gunpowder, and moth-eaten blankets.

The Union was in peril. The Treasury was paying for lame horses. And the War Department couldn't do much about it. Congress saw the need to provide a strong tool to fight fraud. The

False Claims Act was a solution designed to meet a moment where every dollar, boot, and horse mattered to preserve the Union.

Today, the False Claims Act remains among the most powerful tools in the Government's fraud-fighting arsenal in many sectors. Health Care. Defense. Transportation. Its core principle is straightforward—that one should get paid fairly for what one actually delivers—and it certainly met the moment in 1863. And it still shapes the way we think about fair transactions with the Government and the business of health care. The application of the False Claims Act has evolved over time to meet the needs of new eras—from prosecuting contractors who promise a horse but deliver a mule in 1863, to nursing homes that accept Government payment but deliver worthless services in modern times.

Fast-forward to the 1970s, and Federal health care spending had become big business. In 1965, when Medicare and Medicaid were implemented, Government funded 26 percent of the country's health care spending. Ten years later, funding was up to 42 percent. Congress became concerned that health care fraud was a systemic problem, and that the programs could not provide enough oversight. So concerned, in fact, that a sitting U.S. Senator went undercover to investigate health care fraud and abuse. Senator Frank Moss went to three different clinics where he received unnecessary medical tests and services. Based on that work and other findings, Congress changed how the Government would tackle fraud and abuse in Federal health care programs. They established the Department of Health and Human Services OIG (HHS-OIG) as an independent oversight entity.

Inspectors General had served the military for years, but their existence in health care was new. Having an OIG for HHS meant ferreting out health care fraud would not need a Senator going undercover. Nor would it be left to programs whose primary objectives were to administer health care programs. Instead, a dedicated oversight entity would meet the moment of that time. That change propelled us toward the enforcement and compliance structures of today.

Two decades later in the mid 1990s, health care costs were spiraling and fraud schemes were becoming more complex. To control costs, industry began shifting to health maintenance organizations and managed care. Federal health care reform dominated the headlines. Health care and its regulation was growing more complex and more costly.

Demand grew for increased transparency and accountability. And it was clear that more needed to be done to address fraud, waste, and abuse, including bolstering prevention and detection. In 1996, Congress passed HIPAA, the Health Insurance Portability and Accountability Act. HIPAA is perhaps most famous for its privacy protections or perhaps for how often it is misspelled. Many people overlook that HIPAA has two A's, and the first one stands for accountability. Under that first "A," Congress expanded OIG's fraud-fighting authorities and resources. It established formal requirements for OIG to provide guidance to the industry, including binding legal opinions about OIG's authorities.

At a moment of growing complexity, this combination of enforcement and guidance reflected a view that, if Government were going to pursue bad actors more vigorously, it should also help those who were trying in good faith to do the right thing. The Government needed to do more to

engage the industry in their collective mission to ensure that the rules were understood and followed.

HIPAA resulted in many changes that shaped OIG and our program integrity strategies. Following HIPAA, OIG established its own, separate counsel's office and included—alongside branches for civil and administrative enforcement—a new Industry Guidance Branch devoted—as its name says—to the task of providing guidance to the industry. Post-HIPAA, OIG expanded its array of guidance resources. Some of these guidance resources were developed in partnership with AHLA and other private sector associations. But all reflected the idea that we needed to enhance our efforts to prevent fraud, waste, and abuse in the first place. That we could better achieve our mission to prevent fraud, waste, and abuse and protect HHS beneficiaries with a combination of enforcement and guidance.

Since HIPAA, changes in the health care industry and Federal health care programs have sped up: changes in science and medicine, the digital revolution, payment system reforms, and new programs, like the health insurance marketplaces. Along the way, we continued to adapt by introducing sophisticated data analytics to OIG's toolbox, issuing new safe harbors for changing industry practices, or expanding compliance beyond health care to other Government grant and contract programs.

And today, more massive change is afoot. The effects of the pandemic continue to transform many aspects of our society and will likely do so for years to come. And that is certainly true for the health care system. Over the past 18 months, surveys indicate that nearly 75 percent of health care companies are rapidly expanding their digital operations, like cloud computing and advanced data analytics. This, of course, makes sense given the increase in virtual and remote care that we are seeing now and that some estimate may make up nearly 20 percent of all care in the future.

As pandemic experience continues to reshape the health care industry, we at OIG want to apply lessons learned to propel continued improvement for provider compliance. OIG has a demonstrated commitment to helping providers do the right thing, but we believe we can do more.

We can do more to help meet providers where they are at during this time of rapid industry change, and I am pleased to announce what we are doing to modernize.

Simply put, our goal is to produce more useful and accessible OIG guidance, data, and other resources. By tailoring our guidance and other resources to industry's needs, and making it easier to use OIG's resources, we hope to spur improved compliance and innovative approaches that adapt to changes in the health care system. We have some ideas about what would be useful, but we are going to be seeking your input to know what would help the most.

So why does this matter to you?

Done right, focusing our guidance, available data, and other resources to your needs will help you and your clients strengthen compliance. Our goal is to provide you, your organizations, and

your clients with the best information and modern tools possible. We hope we can make processes, like checking OIG's List of Excluded Individuals and Entities (LEIE) or obtaining an advisory opinion, more efficient and easier. We want to help improve compliance programs, allow for better use of data in internal audits, and facilitate a better understanding of fraud and abuse risks. You and your clients help us prevent fraud and abuse, and we want to make it easier for you to do so.

To do this right—to offer the resources most useful to our stakeholders in the most effective way—we are seeking input from a wide range of individuals and organizations with a stake in fraud-fighting and compliance in health care.

Our first step will be a Request for Information (RFI) on OIG's Modernization Initiative to Improve Its Publicly Available Resources. The RFI will be published on our website and in the *Federal Register*. I encourage you to take this opportunity to tell us how OIG's guidance and publicly available resources are used, what are the types and subjects of resources that would be most useful, and how we can improve the way we make our information publicly available. This includes getting your insights on longstanding OIG guidance products, like advisory opinions, special fraud alerts, and special advisory bulletins, as well as on approaches we have used during the pandemic such as FAQs.

In addition, over the last several years, OIG has made it a priority to make data available to OIG personnel—"data at your fingertips" is the phrase we use. Now we are considering whether we can do something similar for our external stakeholders. We are interested in ideas you have about improving usability of OIG data resources like the LEIE; and other OIG products like reports and data toolkits.

We want to look broadly at where we can make meaningful improvements—from the formats we use to provide information, to making resources more accessible electronically on mobile devices, to prioritizing information that should be updated, or considering new products that would help with compliance.

Ultimately, the programs and public will be best served when resources and data needed for compliance, whether from us or other sources, are modernized and available in the most accessible and useable way.

We have not decided what specifically we are going to do. Those decisions will be better informed after public input. Obviously, we won't be able to accommodate every want, or at least not all at once. To give you a better sense of what might be possible, here are three examples of the types of changes we are considering and ask about in the RFI.

First, to help providers who were and are responding to the to the COVID-19 emergency, OIG did something new. We created a frequently asked question process. We took questions about how our authorities would apply to potential arrangements designed to address the pandemic. In response, we issued a series of FAQs on topics ranging from vaccine incentives to providing free equipment for virtual patient care. We are still learning from this experience to identify new ways to get time-sensitive information more quickly to industry stakeholders.

Second, we are seeking input on reimagining the advisory opinion process. Advisory opinions provide a binding legal opinion to the requestor and include a comprehensive legal analysis intended to provide transparency with respect to OIG's assessment. One of the costs of our interactive and careful process in developing these opinions is time—some have said the process is slow and cumbersome. We are considering making changes or adding new options that might help expedite the process and make it more responsive to industry needs.

Third, the LEIE. The 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.

The RFI is the first in a series of actions on which we plan gather input. We also look forward to conducting roundtables—hopefully some in partnership with AHLA—and are considering other ways to collect feedback, such as user surveys.

This modernization initiative will not happen overnight. Instead, we anticipate a multi-step, multi-year process, focusing on the highest value changes first.

I ask that you consider the RFI as a call to action and an opportunity. While OIG is an independent oversight agency and stakeholders may not always like what we do or agree with the positions we take, OIG has a long history of listening to and responding to the health care community. Similarly, the health care community has a long history of providing us with expert, insightful ideas that have helped us shape our regulations and compliance initiatives.

I am excited to launch our modernization initiative with all of you and to work together to meet this moment.

Next, I want to highlight two OIG enforcement and oversight priorities that are also meeting this moment: improving nursing home performance and pandemic response oversight.

OIG is laser focused on spurring significant improvements for the safety, health, and welfare of nursing home residents. The cruel reality of COVID has underscored just how vulnerable patients are in nursing homes and other long-term care facilities. Our work examining nursing homes touches on many problems that pre-date and have now been exacerbated by the pandemic.

OIG recently released a study assessing the devastating impact that COVID-19 had on Medicare beneficiaries in nursing homes. During the month of April 2020, almost 1,000 more Medicare beneficiaries died per day in nursing homes than in April 2019. Overall mortality in nursing homes increased by nearly a third, reaching 22.5 percent in 2020 from 17 percent in 2019. That means 169,291 more Medicare beneficiaries died in 2020 than what we would have expected. In the same report, we also found that the COVID-19 pandemic did not impact Medicare beneficiaries in nursing homes equally. About half of black, Hispanic, and Asian beneficiaries in

nursing homes had or likely had COVID-19, compared to 41 percent of white beneficiaries. And these effects were borne most by dual-eligible Medicare-Medicaid beneficiaries, who tend to be low-income individuals with multiple chronic conditions. 26 percent of dually eligible beneficiaries in nursing homes died in 2020, up from 19 percent in 2019. And 56% of dually eligible beneficiaries in nursing homes had or likely had COVID-19 in 2020.

We are currently conducting work to understand further the impact of COVID-19 on nursing homes, including looks at infection prevention and control deficiencies and nursing homes' reporting of required COVID-19 information. Other work will examine nursing home quality of care, patient safety, and improving the Centers for Medicare & Medicaid Services (CMS) and State oversight because OIG recognizes much is left to be done.

We all know that problems at nursing homes did not start with the pandemic. OIG work has repeatedly raised serious concerns about patient neglect and grossly substandard care, and failures to report incidents of abuse or neglect to State agencies or law enforcement. We have investigated cases of nursing home staff stealing residents' pain medications, causing those residents to suffer unnecessarily. And, most troubling—perpetrators often target residents with health conditions that leave them unable to report the problem. We are working aggressively with our law enforcement partners, including State Medicaid Fraud Control Units, to hold accountable those who endanger and abuse residents.

These beneficiary outcomes are alarming, and OIG has not lost sight of important oversight structures meant to help. CMS suspended traditional comprehensive oversight of homes and shifted to focus on limited infection control surveys. Despite this focus, reports were that infections were rampant among nursing home residents. And State agencies struggled with staffing shortages and mounting backlogs from suspended surveys.

It is critically important that we work together to make progress. 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. Availability of nursing home beds directly impacts hospital discharge planning.

You may be asking yourself what you can do to help. If you work at or represent health care facilities, one practical action you may consider is serving as a resource for nursing homes in your community about their emergency preparedness plans. OIG has found that one area many nursing homes struggle with is responding when an emergency happens. Hurricane Ida has once again brought this problem to the fore, with tragic results for some nursing home residents. We need solutions so that the response to the next storm is better than the last one.

Whether a facility decides to evacuate or shelter-in-place, nursing homes typically need assistance from other community members, like other health care providers, public health entities, and emergency management agencies. If they are not already, your organizations or your clients may be a crucial resource.

We must do better for our nursing home residents. We cannot wait for another pandemic, or another terrible hurricane season, to address long-standing issues like infection control, emergency preparedness, use of anti-psychotics, reporting of incidents of harm, staffing, and effective Federal and State oversight. The time to meet this moment and propel significant change for the Nation's nursing home residents is now.

Finally, COVID-19 oversight and enforcement. COVID-19 response and relief efforts have been enormous. Since 2020, Congress has passed more than $5 trillion in COVID-19 related relief spending. $5 trillion. For context, that is more than all Federal spending in 2019.

Unfortunately, but not unexpectedly– we have seen bad actors exploiting the pandemic to cause harm and line their pockets.

Here, history is again instructive, teaching that when it comes to bad behavior, the more things change, the more they stay the same. I have been reading about the 1918 flu pandemic, and I came across advertisements for unproven elixirs promising a cure or protection - like Miller's Antiseptic Oil and Dr. Pierce's Pleasant Pellets. In that way it is similar and instructive to what we see now. A hundred years ago scammers took advantage of a global pandemic to sell our great grandparents fake cures. The technology was different. They didn't offer fake contact tracing via cell phone, but the concept was pretty much the same.

COVID-related schemes have evolved over the course of the pandemic. Before vaccines were widely available, scammers hawked fake vaccines to people hoping to protect themselves from a deadly virus. Now that safe and effective vaccines are readily available for free, scammers are selling fake vaccine cards. The details will change, but the fraudsters will continually attempt to take advantage of the moment.

In late May, OIG, along with our law enforcement partners, participated in the largest coordinated law enforcement action to combat health care fraud related to COVID-19. A total of 14 defendants in 7 Federal districts across the United States were charged for their alleged participation in various health care fraud schemes that exploited the COVID-19 pandemic and resulted in over $143 million in false billings.

The allegations leading to this takedown are disconcerting. Multiple defendants offered dishonest COVID testing services to Medicare beneficiaries at senior living facilities, drive-through testing sites, and medical offices, prompting the beneficiaries to provide their personal identifying information and a saliva or blood sample. Fraudulent laboratories allegedly misused the information and samples to submit claims to Medicare for unrelated, medically unnecessary, and far more expensive laboratory tests, such as cancer genetic testing, allergy testing, and respiratory pathogen panel tests. In many cases, the test results were never provided to the patients or their actual primary care doctors. In addition, some of the allegations involved kickbacks. One defendant offered kickbacks in exchange for expensive respiratory pathogen panel tests that would later be improperly bundled with COVID-19 tests and billed to Medicare.

As fraud schemes continue to evolve alongside the pandemic, we strive to keep up with the latest iterations and anticipate and guard against the next one. Law enforcement and oversight

agencies across Federal, State, and local governments are continuing to work together. We are sharing data and trends, providing transparency around where the money is going, and responding quickly and aggressively to mitigate schemes that jeopardize public health efforts and the health and safety of people. These joint efforts include working with the COVID-19 Fraud Enforcement Task Force announced in May by the Attorney General. The goal is to not only hold bad actors accountable, but also to put others on notice that fraud will be caught by OIG and our friends.

Beyond fraud, our COVID work includes 12 completed reports and 58 ongoing reviews related to a wide range of HHS programs, funding, and response efforts. This work will offer insights on improving financial integrity for funds used in the COVID response and the effectiveness of the public health response. For example, we are conducting several audits of the Provider Relief and Uninsured Funds, programs that make hundreds of billions of dollars available to support COVID response and relief. Many of the issues we are reviewing may be top of mind as you consider compliance at your organizations over the next year or two. We look forward to providing more information as these audits and studies are finished.

We are also working collaboratively with the Pandemic Response Accountability Committee (PRAC) and its member Inspectors General from multiple Federal Departments to take a holistic look at program integrity issues, such as duplicate payments across programs. The PRAC was itself an innovation by Congress to meet the historical moment of the pandemic. At its core, PRAC is meant to ensure effective oversight of the $5 trillion in relief spending spread out across multiple Federal agencies, with a potential for many cross-cutting issues.

As I conclude, I'll put in one last plug to for you to respond to our RFI. Kicking off this initiative now is especially meaningful as we mark a number of fraud and compliance anniversaries in 2021. October 15 is the 45th anniversary of President Ford signing the law that created the Office of Inspector General at the Department of Health, Education and Welfare. This year is also the 35th Anniversary of the False Claims Act Amendments and the 25th anniversary of HIPAA.

All important milestones that mark our shared progress over the past four and a half decades. Together, we can continue to meet the moment in the fight against fraud, waste, and abuse and to promote compliance.

We look forward to working with you to build on our shared legacy of progress and to strengthen health care for the American public. I hope you have the chance to hear from other members of the OIG team who are speaking during this Forum—they will have much more to offer about our work than I could cover this morning. Thank you again to AHLA for the invitation and enjoy the rest of your conference.