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Good morning to the Health Care Compliance Association (HCCA) community. And thank you, Gerry, for the kind introduction. It is my pleasure to address the compliance community. In June, I was nominated by President Biden. And in February, the Senate confirmed me as the Inspector General for the Department of Health and Human Services (HHS).

It is my great honor to lead this organization of over 1,600 professionals, including auditors, evaluators, analysts, investigators, and attorneys. All are committed to making HHS programs run better—to better serve beneficiaries and better protect taxpayer dollars. I always enjoy addressing the HCCA community. Our missions so closely align. I appreciate how compliance professionals work to make sure your organizations deliver good patient care and are sound stewards of resources. At the same time, you juggle competing needs from owners, boards of trustees, boards of directors, health care workers, and others.

Being the Inspector General of the largest civilian Department amid a worldwide pandemic and unprecedented levels of health care and public health spending is a responsibility I do not take lightly. HHS spent \$2.4 trillion in 2021 or about the same size as the economy of France. The Office of Inspector General (OIG) and compliance professionals know what it is like to take on big responsibilities and use scarce resources wisely.

As an Inspector General, my role is to be impartial and objective. We follow the facts wherever they lead. We provide credible data, information, and recommendations to HHS officials and policymakers. Like every Inspector General, I bring to the role my own core values that will guide how the office operates, our engagement with stakeholders, and our priorities. I want to share a few of those values with you and offer some insights into what you can expect from OIG.

The four values I want to highlight today are people-focused results, pragmatism, preparedness, and transparency.

Especially in times of uncertainty, when there is no precise instruction manual and few easy answers, our core values guide and sustain us.

I credit my grandfather for many of the values that guide me, values that have shaped my career in public service, and values that translate well to the work we are focused on at OIG. Throughout my childhood, my grandfather, Albert Mackenson was the head of the Public Works Department in Edgewater, Colorado. Edgewater spans about a mile in each direction and is close enough to Denver to be able to bike in for work but far enough away to retain a small-town feel.

“Mack,” as my grandfather was known, kept the town of Edgewater running. He was in charge of quite a bit. He ensured that the parking lots at City Hall were striped, so people knew where to park. He helped residents understand city codes for raking leaves and garbage removal. He responded to unplanned incidents such as broken water pipes. His work allowed the town to run effectively and efficiently. And his work ultimately served to improve the lives of the people who lived there. This work made a lasting impression on me and shaped the trajectory of my public service career.

You never really pay much attention to your water or sewer when it’s working, right? You turn on a faucet and water flows out, flush the toilet and the waste drains away. But when it’s not working, you really notice. Mack understood that when critical needs are not met, it creates a significant disruption. His was not always glamorous work, but he did not allocate his time and effort based on what was most glamorous or fun. Instead, he placed value on what was most critical, like being sure the water flows, planning ahead so that infrastructure is sturdy enough to sustain blows, and communicating clearly so town residents knew what was expected of them and where to go if they had concerns.

His values were people-focused, pragmatism, preparedness, and transparency. Those values speak compellingly to the work of oversight and compliance. They are front-of-mind for me as an Inspector General.

And I believe they are values shared by the compliance community that can guide the work we do, collectively, to improve our Nation's health care system.

This morning, I want to first update you on our OIG Modernization Initiative. Then I want to talk about some of the work we are doing that is infused with Mack's four core values.

First, the update on the modernization initiative. OIG's modernization initiative aims to enhance the accessibility and usability of OIG's publicly available data and information. We are investing resources to make program integrity and compliance easier across the health care industry. The modernization initiative builds on OIG's long history of providing information and guidance to the health care industry. As the health care compliance profession began taking shape in the 1990s, OIG recognized the demand for more information and that the developing compliance profession could put more guidance to good use. Since then, OIG and the compliance community have worked closely together—and this partnership has always paid dividends.

The modernization initiative started in 2021 with a needs assessment. We reached out to you. We asked about your needs and preferences, and how we can most helpfully modernize the program integrity and compliance information OIG provides.

We appreciate the valuable feedback that HCCA members have provided. Thank you for taking the time to attend roundtables or respond to our Request for Information. Your feedback will be invaluable to OIG's modernization effort.

Three big takeaways from your feedback are:

First, you value OIG's publicly available resources. That is great to hear! And you are interested in more ways to use them to educate stakeholders. We received feedback about making it easier for you to use OIG's information for a variety of audiences and purposes. You would like more videos, podcasts, infographics, data toolkits, and Frequently Asked Questions.

Second, you would like more ways to connect the dots. It's not enough to have the most recent audit or corporate integrity agreement (CIA). You want more information about how it fits with our other related work.

Third, you would benefit from better, more searchable data and interactive tools that help put more of our information at your fingertips, faster. For example, you said OIG's work plan is valuable information used regularly, but we could make it even better and more useable for you.

As health care grows more complex, organizational priorities are in constant competition. You said that more, better, and up-to-date information from OIG can help keep compliance a top priority at your organizations.

We will continue to work closely with the compliance community and other stakeholders to modernize in a way that best serves the community's needs and our shared goals.

With that update, I want to turn to the values that guide our work and some of OIG's top priorities, starting with people-focused results.

If asked, "what is most important to you about OIG's work", my answer is: the possibility of driving positive change in HHS programs and in the lives of the people they serve. To do this, it is critically important that we get fraudsters off the streets, protect patients from harm, find misspent funds, reduce improper payments, and ferret out mismanagement. We must ensure that taxpayer dollars are being used for their intended purposes to improve the health and well-being of beneficiaries. This is how I think of people-focused results for the OIG.

Achieving people-focused results also means: (1) helping HHS safeguard the integrity of their programs, (2) making recommendations to improve program effectiveness and efficiency, (3) conducting work that shines light on quality of care and health disparities, and (4) helping honest providers who want to do the right thing. Our work does not end at making an arrest, issuing an audit, or publishing guidance. Those actions are starting points. We then amplify them to push for meaningful, systemic change. To make meaningful progress, we must be relentless in our focus on results.

Let me offer some examples from our enforcement portfolio.

Since March 2020, we have been laser focused on preventing, detecting, and taking swift action against COVID-19 fraud schemes. We are combating fraud that jeopardizes public health efforts. These are brazen attempts to take advantage of a pandemic and peoples' fears. OIG and our law enforcement partners have

received thousands of complaints related to COVID-19 fraud. Scams like setting up fake testing sites in parking lots just to steal people's identity or charging patients for fake COVID-19 treatments and falsified vaccine cards. a provider billing over \$100 million to a COVID-19 program for surgeries and services that never happened and did not treat COVID. We've also seen more traditional types of fraud, like improper bundling of laboratory tests and kickback schemes.

In response, OIG, the Department of Justice, the Pandemic Response Accountability Committee, and nearly 30 agencies have been dedicated to disrupting COVID-19 fraud schemes and protecting the people they attempt to prey on. Collectively, we are supporting the Government's efforts to protect the over \$5 trillion in Federal funds spent for COVID-19 relief and hold accountable those who attempt to unlawfully enrich themselves. At OIG, we are focused on protecting the Provider Relief Fund, the Uninsured Fund, and millions flowing to or through HHS programs.

As a further example of people-focused results, over the past decade OIG has devoted disproportionate resources toward oversight related to opioid use and abuse, which remains a terrible scourge in the lives of too many. With action from every corner of OIG, we pressed for improvements to reduce risk to patients from opioid use disorder. As a result, the number of providers prescribing suspiciously high levels of opioids to Medicare Part D patients fell from 401 in 2016 to 98 in 2020.

Sadly, overdose deaths increased during the pandemic. This increase was driven largely by illicit use of drugs like fentanyl. In response, we have broadened our focus to look at beneficiaries' access to treatment for substance use disorder. In a recent study, we found that only 16 percent of Medicare beneficiaries with an opioid use disorder received medication treatment. We are seeing progress but there is still much work to do.

At OIG we are harnessing data and technology to detect and respond quickly to emerging fraud schemes. For instance, we recently uncovered a scheme where laboratories were billing Medicare for expensive, unnecessary, and sometimes unprovided genetic tests. On average, these tests can cost Medicare around \$1,500 each. The alleged fraud in this takedown is nearly \$1.4 billion, and perhaps higher.

OIG worked quickly to shut down this fraud scheme. In just a few short months, OIG took tips from our hotline, conducted comprehensive data analysis, and spearheaded a national law enforcement takedown. We also educated the public to prevent beneficiaries from getting caught up in these schemes. Our actions got results. We saw an 86-percent decline in billing for these tests by the top referrers. Medicare suspended payments for 26 laboratories. And we aren't done yet. We are using every criminal, civil, and administrative tool to recover misspent funds.

To achieve results, our work must be pragmatic. And that's Mack's second value. For OIG, being pragmatic starts by understanding the complex environment in which programs and health providers operate. Our recommendations and guidance must be rooted in facts and be useful in practice. They must be designed to achieve meaningful improvement or change.

Sometimes pragmatic solutions involve tweaking existing systems. And sometimes being pragmatic requires fresh thinking and broader solutions. Actionable change must be rooted in a clear understanding of the problem at hand, realistic, and scaled to the problem it seeks to fix.

At OIG, we use a data-driven, fact-based approach to address the most pressing problems in health care. We think carefully about how OIG's work can be used. We consider how HHS programs can address findings and implement recommendations from a practical, operational perspective. We consider the context in which the program operates. The same is true when conducting oversight of a specific provider, grantee, or contractor. For complex problems, we also consider who else might need to take action to achieve the desired outcome.

We are bringing this pragmatic lens to our oversight of nursing homes. Improving nursing home performance and the care they provide is my number one priority as Inspector General.

We have all watched with distress and profound sadness as nursing home residents and staff suffered greatly during the pandemic—to date over 200,000 nursing home residents and staff have died from COVID-19. Clearly, we as a Nation were not prepared for such a sweeping health emergency. And clearly, the devastation was not contained fast enough. Things must change—and change significantly. We will get past COVID-19, but the significant concerns

about nursing home care must be addressed. OIG oversight over the course of two decades has documented multiple substantial, entrenched problems. These problems recur in fundamental areas like nursing home performance, resident quality of care, and Federal and State oversight.

In a three-part series, OIG is examining the toll that COVID-19 took on nursing homes. We will learn from what happened, spur meaningful and sustainable improvement in nursing homes, and better prepare for future public health emergencies.

The first report in the series found that two in five Medicare nursing home residents had or likely had COVID-19 in 2020. We also demonstrated that the pandemic did not impact residents equally. Black, Hispanic, and Asian residents experienced significantly higher rates of COVID than White residents. By focusing on residents, our report aimed to give voice to those who died or became sick. In doing so, we sought to contribute to the public discussion about the extreme vulnerability of nursing home residents.

For Part 2 of the series, we are taking a comprehensive look at the characteristics of nursing homes hardest hit by the pandemic. Part 3 will address the strategies that nursing homes used to mitigate the unprecedented challenges of COVID-19.

We have reached an inflection point. The time is now to set a new course. Nursing homes can be better. To make them better we must be pragmatic and recognize the very real obstacles facing them. These obstacles include severe staffing shortages, aging buildings and other infrastructure, ineffective oversight, and fractured funding systems, just to name a few. Going forward, we want to raise the bar for nursing homes and nursing home oversight. And to do so in a way that acknowledges and accounts for the complexity and difficulty of nursing home care.

During my confirmation hearing, I outlined a three-part strategy for OIG's oversight of nursing homes. Like any good Government agency, we've given it an acronym. We call it the PRO strategy:

P for Performance—understanding what makes poor performing nursing homes fail.

R for Residents First—ensuring that nursing homes prioritize quality of care and quality of life for residents.

O for Oversight—ensuring that the entities responsible for nursing home oversight—the Centers for Medicare & Medicaid Services (CMS) and the States—detect problems quickly and insist on rapid remediation.

We are coordinating with CMS as it implements the President’s recently announced plan to improve safety and quality of care in nursing homes.

Getting nursing home improvement right will mean using the full range of data, tools, and authorities available to CMS, OIG, States, and others. It will require listening to the perspectives of residents, their families, nursing home providers, and other providers along the continuum of care. Change must be grounded in a clear-sighted understanding of the problems and their root causes. It will require innovative and creative problem-solving. And sustained commitment. OIG is making that commitment.

The third key value is preparedness. It is critical to prepare for problems in advance, like Mack salting roads before a snowstorm that might quickly turn into a blizzard. Being ready for what’s next ensures that an organization can adapt and respond to adversity. Preparedness means having the tools and vision to respond effectively when the unexpected happens. Sometimes, preparedness requires developing a better understanding of risks that are not clearly defined.

At OIG, we focus on identifying emerging and growing risks that might negatively affect the over 100 programs at HHS and the millions of beneficiaries those programs serve. For instance, as COVID-19 fraud schemes emerged and evolved, we warned the public and other stakeholders through fraud alerts and other educational efforts. We knew it was important to get word out so people could take steps to protect themselves.

Preparedness also ensures that an organization successfully confronts change. We recognize that changes in health care do not all move at the same pace. We provide independent and objective information so that policymakers and other stakeholders can better understand and prepare for the effects, including potential pitfalls, of change.

A good example is our recent work looking at telehealth during the pandemic. Rapid expansion of telehealth and new policies led to many questions from many stakeholders. We are conducting reviews to address some of these questions. We want to identify risks that might help policymakers best prepare for the future of telehealth in HHS programs. For instance, an early concern was that expanded telehealth policies would result in patients getting care from providers who did not know them or their medical histories. Our analysts found a noteworthy trend in Medicare claims data responsive to this concern. We issued a data snapshot that found in 2020, 84 percent of Medicare beneficiaries received telehealth services only from providers with whom they had an established relationship. This was somewhat unexpected. But a good indicator that this particular concern about expanded telehealth had not materialized.

Our work examining telehealth continues, including joint work with other offices of inspector general under the auspices of the Pandemic Response Accountability Committee. This work will paint a comprehensive picture of telehealth and program integrity risks across several Federal health care programs.

You can find more information about our telehealth oversight in our work plan on our website, and I look forward to sharing the results of our work as it is completed.

Beyond telehealth, we are looking more broadly at health technology. Understanding the risks associated with technology in a rapidly changing health care delivery system requires a holistic approach that taps into expertise. It requires tapping into expertise within OIG as well as from other Government agencies, the health care industry, and consumers. There is a lot to learn, and a lot of important questions to answer. We are starting to delve more deeply into those questions.

We are developing a health technology oversight strategy to guide our work and ensure that we are well positioned to respond to emerging risks. Key topics we want to explore include:

- the use and effectiveness of technology to drive value for patients and the programs that serve them;
- reducing privacy and cybersecurity vulnerabilities;
- promoting ethical compliance related to health technology; and

- enhancing a data-driven health care system that supports getting the right data to the right person at the right time, including in emergencies.

Ensuring that an organization is prepared to detect and respond to risks is also an essential feature of modern, effective oversight and compliance. Our CIAs reflect this. As compliance programs have become more sophisticated, CIAs have encouraged providers to regularly evaluate their risks, and then use the results of that assessment to tailor their oversight plans. Being responsive to specific risks ensures that an organization's scarce compliance resources are spent looking for potential problems in areas that have the most impact.

Combating health care fraud and improving compliance are most effective when everyone is prepared with the best information available. To that end, OIG will continue to conduct responsive, relevant oversight work; explore new ways to make data and toolkits available to the public; warn patients and providers so they can protect themselves from harm; and find more ways to explain the vulnerabilities that OIG identifies. With enhanced information and more modern tools from OIG, my hope is that compliance professionals can better help organizations prepare for new and emerging risks.

Transparency is the fourth value I will focus on today. Transparency is often the necessary condition for improved responsibility, accountability, and trust, which are key characteristics of high-performing organizations.

As compliance professionals, you have firsthand experience with the value of transparency in detecting problems and improving compliance. Compliance programs have come far over the last three decades. I applaud the compliance profession for its leadership in elevating the quality and effectiveness of compliance programs, and for setting the clear expectation that just having a compliance program is not enough—action is also needed. I also commend the strong emphasis on transparency in effective compliance programs.

OIG's CIAs reflect the importance of transparency in improving accountability. Knowing specifically who is responsible for actions of an organization is a strong incentive that OIG and compliance professionals know can bring about meaningful change. In recent CIAs, individuals—not just organizations—are legally bound to meet the CIA's terms. This has included CIAs for several

individual owners of medical practices, owners of a laboratory company, and an owner of a hospital system. If the terms of the CIA are not met, OIG can hold these individuals accountable by excluding them.

Of course, transparency is more than holding people responsible. It is also about uncovering facts and shedding light on problems. It allows for rapid detection and mitigation of risk.

Transparency can also improve our understanding of barriers to high-quality health and welfare outcomes that all patients deserve.

One important area is better understanding health inequity, a longstanding problem brought to the forefront during the pandemic. We are currently assessing the types of demographic data that CMS, the Centers for Disease Control and Prevention, and other programs collect and maintain. Do these agencies have complete and accurate data necessary to identify and address longstanding disparities for communities of color and those who are economically disadvantaged? OIG is examining this issue to shed light on potential limitations in these programs. Having the right data is critical to understanding how to advance health equity.

Transparency brings me back to the modernization initiative. As we work to update OIG's data and other information, transparency is at the forefront. Mack would have appreciated this initiative—working to make important information clear and easy to find. And endeavoring to put the right tools and data at your fingertips to help you spot risks early and mitigate them effectively. OIG will be transparent about our action items and deliverables. On our website, we will provide a list of modernization actions we plan to implement and when we expect to have them done.

OIG's work and our partnership with the compliance community will be guided by Mack's four values—people-focused results, pragmatism, preparedness, and transparency. If there is one takeaway from this session, it is that OIG is committed to meaningful and sustainable progress. And we count on the compliance community to help us carry that progress forward. At OIG, we can write the guidance or provide the data. But it is up to compliance professionals, attorneys, auditors, and executives to turn those words or data into action and into tangible improvements for patients and providers across your organizations.

As Inspector General, I am excited about the progress OIG and the compliance community can accomplish together. I encourage you to attend the presentations from my colleagues to hear more details about the work I mentioned, as well as other OIG priorities. Have a wonderful Annual Compliance Institute.