

Christi A. Grimm
Principal Deputy Inspector General
Office of Inspector General
Department of Health and Human Services

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Good morning to the AHLA community. And if you're on the West Coast watching, thank you for getting an extra early start to your Tuesday. I am honored to kick off this keynote at the AHLA annual meeting. Thank you to AHLA and the planning committee for the invitation.

I am pleased to join you virtually today to share an update on OIG's work, particularly our oversight of COVID-19-related programs. And then you will hear a conversation with me and Dr. Anthony Fauci, the Chief Medical Advisor to the President and the Director of the National Institute of Allergy and Infectious Diseases at NIH. The conversation with Dr. Fauci will cover a range of issues that are probably top of your mind, both professionally and personally.

I have been thinking a lot about vaccines and how miraculous it is that at the end of June, nearly 150 million individuals in the U.S. have been fully vaccinated and we see COVID-19 cases dropping in most areas of the country. This progress was made possible with the collective effort of and partnerships between the health care industry, government, research institutions, pharmaceutical companies, scientists, the public, and many others.

Vaccines protect us from infectious organisms like viruses that would do us harm. The very first vaccines developed centuries ago did so by introducing a virus or part of a virus into our bodies.

Fast forward to 2020, and the first two COVID-19 vaccines authorized in the U.S. are based on a scientific breakthrough that I find incredibly fascinating. Messenger RNA technology. These new messenger RNA vaccines do not contain

any part of the infectious organism. Instead, they are harmless bits of instructions for your cells to build a protein. The vaccine is the messenger saying, “here is how to build this protein.” Your cells use that instruction to make that protein – and that stimulates our immune system to be ready to fight off the virus, in this case the coronavirus.

When it comes to preventing or fighting disease, the mRNA vaccines only provide the instructions, and our bodies provide the actual protection. I see strong parallels in how those vaccines work and what Inspectors General do in providing oversight of their Departments. And it is similar to the mission or role of health care attorneys, executives, compliance professionals, consultants and others. We serve to protect an organization and the people that organization serves – by showing them how to protect themselves.

And, like the new Messenger RNA vaccines, our work typically involves providing a blueprint and some level of instructions, that if followed, protect now and provide lasting immunity well into the future.

At OIG, we provide insights, recommendations, and advice on how to shore up gaps in programs and systems, a set of instructions for how to fix something. In that way we are similar to the messenger RNA, providing the code and instructions to tackle an immediate or future threat. We can’t, practically, and by law, implement a recommended fix at the Department of Health and Human Services or at a health care entity, but we can provide a blueprint and instructions. I suspect you play a similar role, giving instructions on how to guard against any number of legal, operational, and compliance issues.

You might be thinking this metaphor is a bit of a stretch, but the comparison is both instructive and encouraging. Especially when you consider the potential of the messenger RNA vaccines and how that new technology might improve our fight against many diseases. This advancement is full of world-changing potential that prompts exciting considerations for what might be, especially at this point in history.

In twenty years, historians and leaders in the health care industry and in government will likely view these unprecedented times as an important inflection point. The messenger RNA vaccines are just one part of this potential change.

The question – and challenge for us now – is whether this inflection point is the spot on the timeline where we also collectively address consequential problems that have continued, resulting in significant effects on patients, providers, and health care programs. **Can we provide improved blueprints and instructions to make multi-generational progress after this once in-a-life time crisis?**

I'll discuss four issues in this context. First, ensuring the integrity and effectiveness of the pandemic response and recovery. Second, ensuring quality of care and patient safety in nursing homes. Third, realizing the potential of telehealth. And fourth, advancing health equities.

All four areas present unique opportunities for significant impact and improvement based on the effects of the pandemic. Especially if we work together to provide better instructions to ensure our health care system has the information and tools necessary to address these challenges.

First, ensuring the integrity and effectiveness of the COVID-19 response and recovery. Today, we are nearly 17 months since the Secretary of HHS declared the COVID-19 public health emergency. During that time and across the health care system, we have witnessed the remarkable heroism from clinicians, support staff, and other essential workers. And thanks to their efforts and the vaccine progress I mentioned earlier, we are seeing parts of life return to normal. In light of this progress, we must also remember the toll of this pandemic. The nearly 4 million people globally and over 600,000 Americans who lost their lives due to COVID-19. 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.

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COVID-19 response and relief efforts have been enormous. Both in the consequence of the response efforts on the health and safety of every individual in the country **and** because of the sheer size of the relief funds aimed at bolstering the health of the economy and financial well-being of millions of individuals and businesses. 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. Since the onset of the pandemic, my office has received over 2,400 complaints to our hotline related to purported COVID fraud. 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 working together in unprecedented ways to share data and trends, provide transparency around where the money is going, and to respond 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.

Aggressively pursuing criminal elements is just one part of our **COVID oversight and enforcement blueprint**. We **also** prioritize informing the public about ongoing COVID fraud schemes so that individuals and organizations can **take steps** to protect themselves.

Similar to how COVID vaccines are providing advanced knowledge of the spike protein (so the real virus can't take root), teaching people what fraud schemes look like, prepares them to fend off the bad actors who would harm them. And just as the virus has spread and evolved into new variants, so too do the fraud schemes. The schemes are designed to look believable given the stage of the pandemic and what people want or need at the time.

For instance, in March 2020, when store shelves were emptied of hand sanitizer, the scams offered "senior care packages" complete with hand sanitizer and a face mask. Later, we saw sham contact tracing to steal personal information. And then fake vaccines before real vaccines existed. Now, we see people selling fake proof of vaccinations. As the fraud schemes "go viral" with replicating and evolving variants, we strive to keep up with the latest iterations and anticipate and guard against the next one. For more information on COVID fraud, including our fraud alerts and FAQs, please see OIG'S COVID-19 portal on our website.

Beyond fraud, our COVID work also includes 60 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. We are also reviewing challenges related to the vaccine program, the impact of the emergency flexibilities for many Medicare and Medicaid services, and much more. The goal of this work is to provide vital information to government stakeholders, the health care industry, research institutions, and others so that they can begin to build new protections and improvements to better guard against future public health crises.

Second, 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.

OIG is prioritizing improving the quality of care and safety of nursing home residents. Last week, OIG 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.

We must do better for our nursing home residents, a population who we know are particularly vulnerable to a public health crisis. We cannot wait for another pandemic to address long-standing issues like the need for improved infection control, reporting of incidents of harm, staffing, and effective Federal and State oversight.

The third issue 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 May 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 the government and the private sector grapple with the effects of racial and socioeconomic disparities, I want to share what OIG is doing. 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 have new work underway specifically examining disparities. We are asking questions like whether funding is distributed to account for potential health disparities; whether demographics data – data used to inform public health response – are complete and accurate; and how such data are used to address **inequities.** For example, we just announced a new review of specific CDC REACH grants that are awarded to reduce health disparities among racial and ethnic populations with the highest burden of chronic disease. And we will continue with our longstanding history of work 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.

Fourth is realizing the potential of telehealth. There is a lot of interest from our stakeholders, the health care industry, and others about what worked and what didn't during the pandemic in providing virtual care. Telehealth may be the prime example. Many are considering how to expand coverage based on the experience providers and patients had during the pandemic. Even though our work examining telehealth is not yet complete, discussions are 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, in February we issued a message regarding telehealth based on what we knew at this point in time.

We recognize the potential for improving care coordination and health outcomes by expanding options for accessing health care services through telehealth and other technologies. 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 are key elements that health lawyers and other professionals can help support as organizations adopt and refine their use of telehealth. For instance, 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. Once complete, this work will contribute to building a new blueprint for telehealth 2.0 by helping ensure the potential benefits of telehealth are realized for patients, providers, and HHS programs, while identifying key program integrity factors policymakers should consider.

Before closing, I want to introduce a new initiative to make those messenger instructions from OIG a bit easier to access and use to improve your organizations. The pandemic and a compulsory switch to working remotely for many required us to think differently. For OIG, among other things, we recognized the need to impart rapid information to the health care industry as it responded to a once-in-a-lifetime crisis. During this time, providing more timely

information became less of an aspiration and more of an imperative. We have learned from these efforts and are working to modernize many of our functions.

We believe that the time is ripe for OIG to consider how best to provide timely, actionable guidance, and resources to the industry. Keep your eyes open because we will be looking for your feedback as we re-imagine the various types of guidance and other resources OIG has published over the last several decades. That includes advisory opinions, Special Advisory Bulletins, Special Fraud Alerts, toolkits, compliance program guidance documents, and the COVID-19 FAQs. Your feedback in this area will be critical as we consider how to make future guidance as useful and meaningful as possible for you, your clients, and your organizations.

Additionally, we're exploring a number of ways to improve how OIG data are provided to the health care industry and others. We want to provide things like self-service tools. Tools that provide another option to gain insights from our work but in ways that you decide are most relevant to your work. Last month, on our website we published data related to substance use disorder through a new, interactive web mapping application. This tool can be used to drill down into data about how the substance use disorder epidemic is affecting your city, county, or state, available treatment options, and other information with just a few clicks on a map. We are in the process of using this mapping application for an array of our products.

OIG is also considering a range of ways to adopt other modern data sharing practices. For example, using Application Programming Interfaces also known as APIs, to improve how the 26 million users per year access and use OIG's exclusions data. A move that will allow near-immediate access to this often-used data without having to download a spreadsheet. Your input and insights will also help us find preferred approaches for deploying other APIs, self-service tools, and additional modern data sharing practices to make it easier to access and use program integrity data.

The results of this initiative will not happen overnight. We expect this will be a multi-step process, with the first step being OIG seeking your input. You'll be hearing more from OIG on this initiative soon.

In closing, it has been 17 months of profound disruption and change for all of us. Effects that are still transforming nearly all aspects of society and will likely do so for many years to come. Positive changes from scientists and others brought revolutionary technologies from the development stage into people's arms, hospitals, and our communities. Sectors that have never worked closely together before are doing so now because of our collective mission to respond to the pandemic. And the individual determination to make a difference for others in the face of an unprecedented crisis led millions to volunteer or pitch-in to help their neighbors.

The pandemic demonstrated both the devastating consequences of failing to tackle longstanding issues, but just as importantly: how much of a difference we can make. Not just by working together across government, the private sector, and in new partnerships and collaborations. But also individually and within our organizations.

Now that we see firsthand what is possible in the face of this extraordinary crisis, we should draw on that experience to address the consequential problems covered today. The messenger RNA vaccines and the exciting potential of that advancement is just one example of the possibilities that rose out of the pandemic. Of course, not all positive changes need to be or will be groundbreaking medical technology. But like the function of the messenger RNA, making a difference can start with a single set of better instructions.

Thank you again to AHHA for inviting me to kick off this keynote. And now to the conversation with Dr. Fauci.