Christi A. Grimm, Inspector General Keynote Speech HCCA Compliance Institute in Anaheim, CA Monday, April 24, 2023, from 8:15 to 8:45 a.m.

Introduction

Good morning to the Health Care Compliance Association community. And thank you, Walter, for the kind introduction. It is my pleasure to address you this morning at the 27th Annual Compliance Institute here in Anaheim.

HHS-OIG has a strong commitment toward fostering compliance in health care. In fact, this is at least the 15th time HHS-OIG leadership has spoken at your annual event. Our strong support and consistent presence stems from the very important role HCCA plays in connecting oversight work with your members. Compliance officials, put simply, ensure the health and welfare of the health care we all rely on!

SDP Introduction

I want to start this morning by recognizing a significant compliance milestone: At the end of 2022, more than \$1 billion was returned to the Government through the Health Care Fraud Self-Disclosure Protocol (SDP). Passing this milestone is truly a testament to the success of the health care compliance community, success that is based on the hard work of the people in this room. It is also a credit to the legacy of the many professionals that built HCCA from the ground up, starting nearly 30 years ago.

When you see that billion-dollar mark, think of all the hard conversations you had with your leadership, the many hours you and your teams spent pouring over data, and the years of sweat equity it took to build a culture of compliance at your organization. And think about how that billion-dollar mark does not capture the *future money* you saved your companies and the Medicare trust fund.

OIG established the SDP to provide a fair and effective avenue for individuals and companies that wanted to do the right thing, resolve liability, and provide health care organizations a better option than waiting in stasis for law enforcement to knock at the door. When the SDP was established, we knew there was some interest in using it based on feedback from compliance professionals,

attorneys, and providers. We hoped the SDP would benefit the programs and taxpayers with a more expeditious and efficient return of misspent funds.

The SDP has done exactly that. This is not just about the amount of money recovered, though. It is the sustained use of the SDP that indicates it is working for the Government, for the health care industry, and for compliance officials. This milestone represents how you have made self-disclosure an important tool in your toolbox.

We know that sometimes it is not easy to convince executive leadership of the merits of disclosing a violation to the Government. We hear about the stress and burnout that comes with the compliance role. Indeed, the role that you play in moving individuals toward accountability and in generating a culture of compliance takes persistence. This milestone is evidence that the work you do is worth the hard effort. Meaningful compliance oversight pays dividends, not only for Federal health care programs and taxpayers but also for health care organizations. Thank you for all that you do and for your significant role in meeting this milestone. We quite literally could not have hit the billion-dollar mark without you.

Roadmap

I am speaking with you this morning to call on your partnership once again. I want to speak to the crucial role that compliance can play as a bright and steady North Star during a time of intense pressure, uncertainties, and change. That compliance North Star can help keep the health care industry focused on the right things, like quality of care and sound fiscal management.

I then want to zero in on two key areas where compliance and compliance officials can play a crucial role to make meaningful, lasting progress: (1) improving nursing homes and (2) strengthening program integrity in managed care. OIG sees an increased need in these areas for know-how and the can-do approaches that you use every day.

Complex Health Care Landscape

As the health care system reboots following years of a public health emergency (PHE), familiar and new concerns abound. There are concerns about quality and access to care, increasing expenditures, competition, a workforce stretched thin, and new, complex business models. The stakes are high for health care companies, payers, and ultimately for patients.

This is an incredibly dynamic time for the health care sector. A combination of rapid change and longer-term trends is transforming the industry. It can be hard to keep up, to know which change is lasting and which trend is fleeting, especially as the industry approaches the end of the PHE.

Structural changes include the increasing number of individuals enrolled in managed care models in Medicare and Medicaid, consolidation, the evolution of value-based care, and growth among nontraditional players such as health-technology companies and payor-owned providers.

A recent story in Modern Healthcare highlighted the sheer growth in the number of providers that are employed or affiliated with health plans. Some are calling them "pay-viders." CVS Health added 10,000 pharmacists and primary-care professionals in 2021, and more are coming due to its recent acquisition of Oak Street Health. Humana served more than 200,000 patients in more than 200 primary-care clinics. And UnitedHealth Group via Optum is the largest employer of physicians in the country, with more than 70,000 providers.

Of course, we cannot overlook the seismic changes and challenges wrought by the COVID-19 pandemic. Providers will continue to face challenges as they emerge from the PHE to confront a changed landscape. As waivers expire, providers must chart a course forward to assure compliance with regulations that were effectively suspended or significantly modified during the PHE. Unwinding will not be an easy task after the past 3-plus years.

Yet even in the face of this turbulence, health care has generally been seen as a "safe bet" from an investment perspective. More investors, such as private equity, have jumped in. The presence of private equity in the industry is increasing, with more than \$1 trillion dollars in 8,000 deals over the past decade. Private equity investment in nursing homes and other sectors is prompting tough questions about its impact on the quality of care that is provided, as well as the potential for profit considerations to take priority over patient care. Even traditional health systems are moving to invest in new areas of the industry, such as health plans.

It can be virtually impossible for health care organizations to succeed in this type of environment without a clear way to navigate through problems that will inevitably occur. It requires practiced risk assessment and expert compliance methods to ensure that health care providers deliver high quality care and use sound financial management, as well as reduce organizational risks that may arise from powerful new incentives. Compliance can be the compass to point the way, to act as a stabilizing counterbalance to pressures that can tempt organizations into troublesome directions

and lead to decision making that imperils patient care and puts organizations at risk of noncompliance, corner-cutting, or worse.

Areas Where Compliance Can Have Major Impact

Against that backdrop, let me turn to two areas in which OIG needs help steering the industry toward the compliance North Star: nursing homes and managed care. These are areas where a compliance compass can help redirect entities that have gone off course or help chart a fresh course.

Nursing Homes

We know that compliance helps an organization remain focused on providing high-quality care.

OIG work has pinpointed breakdowns in quality of care across many health care sectors. Perhaps the most pronounced example, given the experience of the past 3 years, is nursing home care.

You have heard me say that nursing homes are my top priority. Improving nursing home care for those who need it is front-of-mind for the OIG team. But we cannot do it alone: Opportunities abound for compliance professionals to make a difference.

Many nursing homes in the United States provide excellent care. It is important to acknowledge this and to learn from nursing homes that do a great job providing safe, dignified, respectful care. But in decades of OIG work, we have found that nursing home residents are too often subjected to poor quality and unsafe conditions. These problems are entrenched and difficult. Our work has long identified concerning weaknesses in areas such as staffing, infection control, and emergency preparedness. There are also challenges ensuring that deficiencies are promptly flagged and remedied, and that incidents of abuse and neglect are reported as required. The COVID-19 pandemic exacerbated longstanding problems and added new ones, with devastating results for nursing home residents.

Poor nursing home performance leads to ripple effects for the provision and cost of health care in other settings, including hospitals. Our work demonstrates that improvement in quality and safety is possible with better guidance and oversight.

No one should dread having to live in a nursing home or needing to find a nursing home for a loved one. Yet public opinion polls have found that 71 percent of older American adults say they are unwilling to live in a nursing home in the future. Think about that: 71 percent.

Part of the solution is finding better ways for elderly and disabled people who need nursing home care to remain in their own homes or with family, with needed care and support. But this will not work for everyone.

To guide our oversight of nursing homes, OIG has identified a three-part framework that we refer to as the PRO framework. PRO stands for Performance, Residents First, and Oversight.

The first focus area is understanding the incentives and causes that drive poor nursing home performance, and what can be done to strengthen standards and incentives. This area focuses on nursing home operations and incentives. For example, we are conducting new work to better understand the reporting of related party costs, as well as new work examining how nursing homes use Medicaid funding to provide direct patient care. Among other things, this work aims to shed light on the relationship between spending on care and ownership structure, including private equity. Compliance professionals are well-positioned to be looking closely at compliance with requirements related to financing and delivery of direct patient care.

The second focus area—putting Residents First—drills down to the bedside experiences of residents and their loved ones. We want to help ensure that nursing homes prioritize quality of care and quality of life for residents. Compliance professionals can make an enormous difference by identifying risk areas and steps nursing homes can take to reduce risk and improve the experiences of residents and their families. Current OIG work is focusing on an alarming concern about potential falsification of schizophrenia diagnoses to justify the use of antipsychotics. We are also continuing rigorous work to curb the deplorable abuse and neglect of nursing home residents. That includes enforcement through the False Claims Act for the provision of substandard or worthless services, and exclusion of nursing home owners and operators that egregiously fail their residents.

The third focus area is ensuring that those responsible for frontline oversight of nursing home quality and safety are able to detect and remedy instances of noncompliance and substandard care quickly and effectively. CMS and State survey agencies are critical eyes and ears on the ground to safeguard resident well-being. Extensive OIG work has revealed backlogs and performance

challenges for CMS and the survey agencies. But protecting nursing home residents is not solely the Government's job. Residents and loved ones depend on nursing homes and their care teams to deliver high quality, dignified care. Residents need to trust that nursing homes take quality, safety, and resident well-being seriously. Compliance activities that are laser-focused on putting residents first by detecting and correcting problems can make a big difference.

Performance, Residents First, and Oversight: These markers help us and can help you ensure that the focus remains squarely on delivering high quality care in nursing homes. And while we identified this framework for nursing home oversight, I'll offer that broadly it makes sense as a compliance framework for many types of providers.

Success in raising nursing home performance will require broad collaboration with partners and stakeholders across Government, the nursing home sector, and the broader health care industry. It will also require partnerships with residents and their families as an underused asset for improving care.

If we collectively get this right, we can remake the nursing home experience for seniors, people with disabilities, and their loved ones.

Managed Care

Now let me turn to managed care. It is a booming part of health care for which a rigorous compliance focus on financial integrity is sorely needed. With significant growth have come new financial pressures, increased market competition, and new players. These changes heighten financial pressure on health care organizations.

As compliance officials, you help your companies navigate and avoid the temptations of incentives created by these changes. You are experts in charting the course to strengthen financial integrity. Compliance professionals can help new players—and old players taking on new roles—manage financial integrity risk, regardless of the surrounding environment.

I understand that many of you may come from hospitals, physician practices, and other providers and suppliers. With the growth of Medicare and Medicaid managed care, program integrity risk in these programs is not limited to private plans and insurers. If your organization serves Medicare or Medicaid patients, the issues in managed care will likely affect you, if they have not already. Medicare Advantage now covers more than 30 million Medicare patients and is expected to cover

50 percent of all enrollees soon. And nearly 80 percent of Medicaid patients receive health care services through insurance plans.

The expansion of managed care, especially over the last decade, has come with growing pains that have strained program integrity and highlighted compliance weaknesses. OIG's audits, evaluations, and investigations have demonstrated that risks of fraud, waste, and abuse in managed care are real and significant.

Last month, I had an opportunity to address a group of managed care plan executives. The crux of what I told them is that they need to catch up on compliance. Managed care plans and vendors that participate in managed care face increased scrutiny and would therefore benefit from stepped up compliance efforts.

Scrutiny and oversight are not just coming from OIG: Our colleagues at DOJ are actively investigating complaints against Medicare Advantage plans. Members of Congress, the Government Accountability Office, the media, and the qui tam bar have all recently highlighted widespread fraud and abuse concerns in Medicare Advantage.

Let me highlight a couple of risks in managed care that may be germane to your organizations based on OIG's work. Conduct related to the Medicare Advantage risk adjustment program raises significant concerns for patients and providers, and for the financial integrity of Medicare.

First, though, there is no doubt that risk adjustment is important to the success of Medicare Advantage. It is designed to compensate plans for the increased costs of treating older and sicker beneficiaries and to discourage plans from preferential enrollment of healthier individuals. If applied correctly, paying more to plans for caring for people with serious medical needs preserves and expands access to medically necessary health care services.

Nevertheless, our work has demonstrated there are significant problems with risk adjustment. Simply put, the financial incentives created by risk adjustment may be driving upcoding in the severity of diagnoses to garner additional payments.

For example, when we looked at 20 insurance companies that received \$5 billion in risk adjustment payments in 2017, we saw something interesting: These 20 companies received more than a half-billion dollars in risk adjustment payments for patients that plans had diagnosed as having serious mental illness, such as major depressive, bipolar, and paranoid disorders. Yet no service

records showed those same enrollees had received treatment for these serious conditions. The same applies for other serious illness and disease.

This is a troubling gap for these patients and for the health care professionals that care for them. If plans have information about an enrollee's health status, health care professionals should have this information to ensure appropriate care can be provided. Or if the diagnoses do not reflect unmet needs, then equally troubling is the accuracy of the diagnoses and why they were reported in the first place.

I suspect that those of you who work with hospitals and physician practices are wondering how gaming and misconduct by plans in risk adjustment affects you. Well, health systems and physicians have gotten into trouble because of agreements they've entered into with managed care plans.

For example, OIG and the Department of Justice investigated a case involving arrangements between Medicare Advantage Plans and a health care services provider and several affiliated entities. I'll refer to them collectively as the provider. The Government alleged that the provider knowingly submitted unsupported diagnoses codes, which caused inflated payments to be made to both the plans and the provider. The Government further alleged that once the provider became aware of the unsupported codes, it failed to take sufficient corrective action to identify and delete additional unsupported diagnosis codes. Ultimately, this arrangement proved costly for the provider, which agreed to pay \$90 million and enter into a stringent corporate integrity agreement (CIA) with OIG. The CIA requires, among other things, that an independent review organization annually review a sample of the provider's Medicare Advantage patients' medical records and associated diagnoses data.

There are significant dollars at stake in managed care when assessing these risks. For example, diagnoses that Medicare Advantage organizations reported only on chart reviews—and not on any service records—resulted in more than \$6.5 billion in risk-adjusted payments in 1 year. That is a significant amount of Medicare dollars associated with questionable practices. Relatedly, we routinely get referrals and complaints from whistleblowers and others regarding risk adjustment practices. This includes insiders who see fraud risks or unethical conduct and may be frustrated or disillusioned by their organization's failure to address them. Because the risk adjustment dollars are so large, many insider referrals have led to significant settlements with plans, providers, and

others to resolve allegations of intentional conduct purposefully designed to increase risk adjustment payments.

We know that the pressures to financially succeed build with industry disruption. As insurance companies or new players increase or change their footprint—and make lots of money in doing so—health care organizations may be increasingly pulled off course to focus on the new thing rather than the right thing. As managed care continues to grow and the associated dollars get larger, providers may be offered new ways to partner with plans to increase revenue in ways that did not exist under a fee-for-service system. When assessing those new options, know that scrutiny in managed care does not end at the doors of insurance companies. Organizations that do business with managed care plans should be adapting compliance programs to reflect the growth of managed care in Medicare and Medicaid.

Modernization Initiative Update

We recognize that to make a difference on issues such as nursing homes and managed care, the partnership between OIG and the compliance industry must remain strong. The information our work provides can help you convince your organizations to course-correct as needed and focus on quality of care and financial integrity.

During my remarks at the 2022 Compliance Institute, I shared with you that transparency is at the forefront of the work that we do. I explained our plan to put the right tools and data at your fingertips to help you spot risks early and mitigate them effectively. We've received your feedback at roundtables and through other avenues. And we've been acting on what we have heard.

We have taken a number of steps since last year. Let me highlight two updates that may be of particular interest.

This morning, we are releasing a telehealth program integrity toolkit to aid providers, plans, and others in identifying risks associated with telehealth billing. This toolkit is a good example of the new resources we are creating to support compliance. And it is the type of information you asked for more of from OIG. As telehealth has become a bigger, more permanent part of health care delivery, we recognize stakeholders want more information about its potential risks and benefits. We have been conducting extensive reviews of telehealth in Medicare. Telehealth holds great

promise for the efficient delivery of quality health care. But it behooves us all to be alert for possible fraud, waste, and abuse as this mode of delivery expands.

Based on the telehealth program integrity report we issued in September 2022, our new toolkit gives practical information on how health care organizations can analyze their own telehealth claims data to identify indicators of potential fraud risk, such as billing for a high number of hours for each telehealth visit. That way, health care organizations and your compliance teams can help mitigate risks as your providers and patients continue to adopt telehealth as a permanent part of your delivery options.

Finally, and of particular interest to this group, today we are publishing our plan to update OIG's Compliance Program Guidance (CPG) documents. Our CPGs are among our most popular guidance documents. And although they remain good guidance, they have not been updated in some time. Updated CPGs have been among the most requested modernizations.

Our plan is twofold. First, we aim to publish later this year a new General CPG with tips and pointers applicable to all industry sectors. Then, starting next year, we will roll out supplemental CPGs with tailored, industry-specific content. The first two on deck are managed care and nursing homes CPGs, with others to follow. These new CPGs will be modern, web-based publications that are an upgrade from the stodgy, three-column Federal Register notices. More information about our plans can be found on our web page. Our Modernization Initiative work is just beginning, and we will continue to engage with you as we advance this important work; there is much more to come.

Conclusion

In closing, I remain excited about our ongoing partnership and the many new opportunities we have to work together to improve health care compliance. Together, we can help ensure that health care companies remain compliant and do not drift off course during this turbulent, challenging period for the industry. Compliance professionals can help improve nursing homes for people who need them, so that the elderly and people with disabilities have peace of mind, quality of care, and quality of life. Compliance professionals can help counterbalance powerful incentives in managed care that raise financial, legal, and quality of care risks. And we can all work together to navigate the new telehealth waters.

We rely upon compliance professionals who are entrusted within their respective organizations to serve as compliance North Stars—pointing the way toward effective, efficient, high quality health care for everyone.

I encourage you to attend the presentations from my OIG colleagues for deeper dives into some of the work I mentioned, as well as other current work and priorities. These are among the Government's top experts in compliance, and I am so pleased that they are here not only to present our work but also to continue to learn from the compliance professionals attending this important program.