

***Assisted Living and the Law* — Key Takeaways From the OIG's New Compliance Guidance for Nursing Facilities**

**Hosts: Cal Stein and Emma Trivax**

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**Cal Stein:**

Hello, and welcome to *Assisted Living and the Law*. The podcast series that discusses legal considerations within the long-term care sector. I am your host, Cal Stein, and I'm a litigation partner in the health sciences department at Troutman Pepper Locke. I work with a broad variety of clients in the healthcare space in matters involving litigation and government investigations. I also do quite a bit of counseling work particularly on the compliance side of things where I advise clients in advance of issues arising, so they are prepared to address and remedy them before they ripen into litigation or an investigation.

In my career, I have represented a number of nursing home and skilled nursing facility clients, as well as executives at both.

**Emma Trivax:**

Hello, and thank you for joining us today. I am Emma Trivax, an attorney in Troutman Pepper Locke's Healthcare and Life Sciences Department, and I practice transactional and regulatory law. I represent a wide range of healthcare providers including, of course, long-term care facilities. You'll see me advising on multi-state licensure matters, HIPAA, fraud and abuse analyses, and large-scale mergers and acquisitions.

In today's episode, we delve into the complexities of compliance in the nursing facility sector, particularly some new guidance that the Department of Health and Human Services Office of Inspector General recently released that is specific to the long-term care sector.

**Cal Stein:**

Yes, that's right, Emma. In this installment, we're going to be talking about the industry segment-specific compliance program guidance from HHS-OIG for nursing facilities, and this release came just this past November. Now, that title is a bit of a mouthful. Throughout this episode, we're going to be referring to that guidance document simply as the ICPG. We're going to spend some time today talking about it, the new pieces of guidance that appear in it, how they impact nursing homes, skilled nursing facilities, and other long-term care facilities.

But before we get into those details, why don't we start with some basics about the ICPG, Emma?

**Emma Trivax:**

Yes. So, let's start with that historical context. The nursing facility ICPG, it's really hot off the presses, by the way. It was just released this past November. That was just issued by the OIG and it provides an updated and centralized voluntary compliance program guidance for nursing facilities. What that means is it's building upon prior guidance issued in the year 2000 as well as the year 2008, addressing key compliance risk areas and offering recommendations for mitigating those risks.

The nursing facility ICPG is designed to really help nursing facilities identify their own risks and implement effective compliance and quality programs to reduce those risks. It covers a wide range of topics, including quality of care, Medicare and Medicaid billing requirements, the federal anti-kickback statute, as well as several other compliance considerations. The guidance really emphasizes the importance of integrating compliance and quality programs to monitor adherence to the laws and regulations that govern health and safety standards, resident care, and quality of life.

**Cal Stein:**

Yes, thanks, Emma. So, I do want to elaborate on some of the key compliance risk areas that the OIG has highlighted in the ICPG. But before I do that, I do want to quickly address two things that you just mentioned. First, The ICPG that we're going to be talking about is something, as you said, of a continuation of some prior guidance that the OIG issued in 2000 and 2008, both of which was nursing home-specific guidance and then a supplement to that guidance.

But this ICPG is also a continuation of the OIG's general compliance program guidance, sometimes called the GCPG that was released a year ago in November of 2023. Now, the GCPG applies as you would expect generally to all individuals and entities in the healthcare industry. The ICPG that we're discussing today is more tailored to nursing facilities, but it should still be read in the overall context of the nursing home-specific guidance from 2000 and 2008 and the general guidance of November of 2023.

Second, Emma, you mentioned, I think, that the ICPG is basically voluntary. I mean, it's compliance guidance, but it is, in fact, voluntary. And this is a question we get a lot. So, I want to address it right up front, which is, do we have to comply with it?

Now, on the one hand, the answer to that question is no. I mean, these are not laws. They haven't been passed by Congress, they haven't been codified in the CFR. But on the other hand, while voluntary, the ICPG is a comprehensive list of what the OIG expects to see in terms of facility compliance. If a facility out there were to choose not to voluntarily comply with them and it were to have an issue or an investigation, there would certainly be consequences for that failure, namely not living up to the OIG's expectations.

With that, let's now turn to discussing some of the key compliance risk areas that are highlighted in the ICPG. Let's start with one you mentioned, Emma, which is quality of care and quality of life residents. This includes ensuring things like appropriate staffing levels, which is something we've discussed on a prior episode in connection with the new staffing mandate from CMS, but

also developing individual resident care plans, managing medication, and maintaining resident safety.

In my view, this compliance risk area is number one with a bullet in this ICPG. This has long been a focus of the OIG and other government regulators, but even more so recently. One of the major themes, if not the major theme of the ICPG, is that the OIG is now looking for facilities to integrate and tie together the compliance function with its quality assurance and quality control functions. We will talk a little bit more about that later.

Some other key compliance risk areas that are highlighted in the ICPG, as you mentioned Medicare and Medicaid billing requirements, ensuring compliance with all the billing regulations to avoid submitting false claims, nothing new here but renewed area of emphasis and some wrinkles, and then federal anti-kickback statute compliance. More emphasis from the OIG about the vigilance needed when evaluating arrangements with referral sources and recipients to avoid unlawful payments for referrals. Then there are some other risk areas that are addressed related party transactions, the physician's self-referral law, sometimes called the Stark law, HIPAA privacy and security rules, and also civil rights compliance.

**Emma Trivax:**

So, you mentioned how important that first bullet was, the quality of care and quality of life note. I want to dive a little deeper into that, right? As you said, we've talked about this in more depth on a previous podcast episode, but really, it's true. One of the primary challenges is maintaining adequate staffing levels and it's likely going to get harder. But research has shown a clear correlation between those staffing shortages and substandard care and nursing facilities will often operate because they have to in an environment of staffing shortages, high staff turnover, and workforce burnout, all of which can really exacerbate those challenges associated with attracting, training, and retaining an adequate and qualified workforce.

I'm sure that's what that CMS staffing mandate is getting at, and why it is also emphasized here. But high turnover rates among nurse aides who provide most of the direct care in nursing facilities can often result in residents frequently receiving care from new staff or agency staff who just lack the experience and the institutional knowledge of individual residents and their needs.

**Cal Stein:**

Yes, those are all great points, Emma. So, let's talk a little bit about what the ICPG recommends for addressing some of these challenges. The ICPG actually does provide some recommendations. First, developing and implementing comprehensive policies and procedures that address key risk areas. Second, providing regular specific and comprehensive training for all staff members on compliance and quality requirements. Third, conducting regular internal reviews and audits to ensure compliance with the laws and regulations. Fourth, establishing clear communication channels for reporting compliance concerns and ensuring timely and thorough responses to issues. Then fifth, integrating compliance and quality functions to monitor and improve adherence to health and safety standards.

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**Emma Trivax:**

I'm glad you said that, because I'd like to talk about how the ICPG suggests those nursing facilities handle the integration of compliance and quality programs. So, the ICPG emphasizes the need for collaboration and alignment between compliance and quality functions. It really recommends that nursing facilities establish compliance committees that support both compliance and clinical leadership in developing and maintaining strong lines of communication. You'll hear us talk about this a lot throughout today's episode, but communication is so important to really work these ICPG recommendations into your facility. Some of this communication can include regular reviews of compliance, quality, and safety data, and ensuring that compliance and quality initiatives are coordinated to eliminate redundancies and improve efficiency.

**Cal Stein:**

Yes. I want to spend a little bit longer on this topic, Emma, this topic of the integration of compliance and quality functions, because I actually think this topic, this theme that is woven throughout the ICPG actually implicates another large theme that we see repeated throughout the ICPG. And that is, it's actually a new theme. What it is, is it relates to multiple specific and repeated references by the OIG throughout the ICPG to integrating individual owners, individual operators, and individual investors in these long-term care facilities into the compliance function.

As I mentioned, this occurs throughout the ICPG. It comes in the form of multiple general warnings that nursing facilities should be focused on "corporate level compliance," which requires individual owners, operators, and even investors demonstrating their commitment to compliance. It also comes in the form of warnings about specific individual conduct and specific changes to the ICPG targeting individuals.

So, for example, the ICPG that was just released this past November explicitly calls out the OIG's concern over something called tunneling, which is the practice of facility owners, operators and investors misrepresenting their profitability by overstating payments for operational expenses that are then funneled to related parties. The OIG is very clearly focused on these types of payments, which may be used, it says, to unjustly enrich these individuals.

Now, the ICPG also highlights the fact that it is expanding the definition of responsible individuals, which is used throughout the guidance document, to include investors, which is a change in the ICPG and one that the OIG describes as being of "paramount importance."

So, what does this mean in practice? Well, on its face, I think it means that OIG is likely to prioritize enforcement activity against individuals in addition to facilities, and those individuals are not just going to be the people with operational control over the facilities, though those people still very much are at risk, it's also going to include the individuals who are ultimately responsible for the facilities, both at the individual facility level and also at the corporate level in the case of chains of facilities.

What can individuals in leadership or management or even investor positions do to be protecting themselves using this ICPG document as guidance? Well, the ICPG makes clear that the OIG is going to be looking for a quote "demonstration of commitment to compliance" by all of

those individuals, whether they be in leadership and management or just an investor. The more focus that is given to compliance the better.

At one point, the ICPG actually suggests that these individuals should be focused on compliance and safety as much as they are focused on financial and profit indicators. Therefore, individual owners, operators, and investors really should be documenting all the time that they can devote to compliance and to safety, including at leadership meetings, investor meetings, board meetings, et cetera.

So, for example, there should be robust meeting minutes that document compliance and safety discussions. Beyond the meetings, to the extent there are emails or other communications tracking profit and financial metrics, there should also be equal attention or at least near equal attention devoted to compliance and safety metrics. For investors in particular, one of the ways that the OIG suggests that they demonstrate their commitments to compliance is by actively engaging with facility leadership and facility operators about compliance and safety functions.

What that means is investors should really be taking on a more active role in questioning a facility's compliance with federal health care program requirements and fraud and abuse laws, as well as making inquiries to ensure that adequate resources are in fact, being devoted to the compliance and quality function at both the corporate and individual facility levels.

**Emma Trivax:**

That's really fascinating, and I think it gives investors quite a lot to think about as we move into the next year, deals are happening. How can investors keep this front of mind when they are investing in these long-term care facilities?

Wow, that's really interesting. Something else that came to my mind when you were talking about this was you've got both the ownership and the individual approach and that reminded me of something else you said about individualized resident care plans and the ICPG really highlights individualized resident care plans and focuses on how they really are a huge foundation for compliance. Developing and implementing those appropriate care plans, it's crucial for providing high-quality person-centered care.

The requirements of participation really mandate that nursing facilities develop and implement comprehensive care plans that address the medical, nursing, mental and psychosocial needs of residents. These care plans must be regularly reviewed and updated to reflect changes in resident conditions and failure to develop and implement sufficient care plans can lead to standard care, submission of false claims, and government enforcement actions.

Now, none of this is new information, but the ICPG helps us determine how do nursing facilities improve their care planning processes in putting together those individualized care plans? Well, nursing facilities have actually reported several strategies to mitigate the risks associated with ineffective or inadequate care plans. The first one is it goes back to what I said earlier about communication, but develop policies and provide training to encourage open communication and care planning meetings between direct care providers and interdisciplinary team members.

I actually know a lot of facilities who will do monthly or even weekly interdisciplinary team meetings just to make sure that that communication is happening. And that leads us to the second point where we should document that communication, document the care planning meeting, including notes about the discussions, particularly reflecting the preferences of residents, family members, and guardians. We really can't emphasize this point enough. Documentation is everything for nursing facilities and really is highlighted throughout this ICPG.

The last note is organizing meetings to promote physician engagement and supervision of each resident's care and to discuss care plans for specific residents. This again just brings everyone together involved, the direct providers, the physicians, the nurses, everyone on that team so that there is no question left unanswered when it comes to developing these resident care plans.

**Cal Stein:**

Yes, I mean it sure sounds like effective communication is really the key, which I know is something you mentioned earlier in this episode. You just mentioned it again. And candidly, I know it's something that we have both seen throughout our careers when dealing with these types of issues in the context of internal and government investigations of these long-term care facilities as well as other issues that arise. But what about resident activities and how they factor into compliance and quality of life? I mean, what does the ICPG have to say about that?

Well, engagement in socially and cognitively enriching activities is, of course, essential for residents' quality of life and well-being, which is all woven throughout the ICPG. The activities, they provide needed social interaction, they help build relationships among the residents, they promote a sense of community, they stimulate cognitive abilities and contribute to maintaining and improving physical health and mental awareness.

Look, nursing facilities are required to have activities programs under the requirements of participation. A robust activities program can actually significantly enhance residents' quality of life and overall well-being, which will make it easier and more effective for the facility to comply with these ICPG lines.

**Emma Trivax:**

Really interesting. I know how important that is and it just makes me think as we go in and right before we wrap up, I want to touch on some final thoughts about what nursing facilities really should focus on to ensure compliance and good quality programs and really try and implement what this ICPG puts into place.

So, in my view, nursing facilities need to prioritize creating that culture of compliance and quality that's supported by leadership at all levels. Like Cal mentioned, it goes up pretty high, it goes up to investors. That really, really matters here. This includes ensuring that the compliance officers themselves have necessary experience and authority that they are providing ongoing training and education, and regularly assess and update compliance and quality programs to address new risks and regulatory changes. Things change all the time. So, it's important to keep someone who is very engaged, has their foot on the gas, and is ready to implement and update



their programs. By doing so, nursing facilities can better protect their residents and ensure very high standards of care.

**Cal Stein:**

Thank you, Emma, for joining me here today on this podcast. I also want to thank everyone for listening and tuning in to *Assisted Living and the Law*. If anyone has any thoughts, comments or questions about this series or about this episode, please contact either me or Emma. Please subscribe and listen to this podcast and other Troutman Pepper Locke podcasts wherever you get your podcasts, including on Apple, Google and Spotify. Thank you for listening. As always, stay informed and stay healthy.

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