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In Updated Self-Disclosure Protocol, OIG Lays It All Out for Providers with Violations

The HHS Office of Inspector General takes some of the guesswork out of resolving potential Medicare transgressions in its updated Self-Disclosure Protocol, unveiled April 17. OIG explains how damages are calculated for specific types of misconduct and generally offers providers a settlement amount of 1.5 times the overpayment. In return for the transparency and a "small" multiplier, OIG expects providers to come clean about their noncompliance, says Tony Maida, deputy chief of the OIG's administrative and civil remedies branch. "If you are going to disclose into the protocol, you should be prepared to enter into a settlement and disclose the conduct," he tells *RMC*. "We don't issue parking tickets."

Established in 1998, the Self-Disclosure Protocol (SDP) allows providers and suppliers to reduce their liability under OIG's civil monetary penalty laws (CMPLs) and avoid Medicare exclusion by confessing their (potential) sins. There are at least 26 different CMPLs, penalizing kickbacks, false claims, Stark self-referrals, employing excluded people, copay waivers, payments to physicians to reduce services, patient dumping and other offenses.

Since 1998, OIG has resolved more than 800 self-disclosures that resulted in $280 million in recoveries and required only one corporate integrity agreement stemming from the 235 SDP cases resolved since 2008. "Going through a self-disclosure is another indication the provider has a living, breathing compliance program," Maida says.

Updated SDP Is More Transparent

At its inception, the SDP described how providers that may have run afoul of these laws should conduct their investigations, quantify damages and report back to OIG to qualify for the benefits of coming forward. The new version has more detail in these areas, including the use of statistical sampling, damage calculations, and how to address a provider's inability to pay a settlement amount.

"This is pretty good. While I am not keen on all their answers, they have answered a lot of recurring questions," says San Francisco attorney Judy Waltz, with Foley & Lardner LLP.

The updated SDP specifies that providers will generally pay 1.5 times the single damages — although greater penalties may be levied. While Waltz says the 1.5 multiplier promise is significant, "they are using that as their floor, not their ceiling." The settlement amount will depend on the facts of the case and the provider's cooperation and conduct during the disclosure process (e.g., submitting documentation in a timely manner), Maida adds.

The updated SDP also requires providers to move faster. OIG now resolves disclosures in 12 months and to keep things rolling, providers must submit the results of their investigations and damage calculations within 90 days of their initial submission, instead of 90 days after their acceptance into the self-disclosure program. "This updated SDP will require them to invest more time and resources sooner in the process than they had to in the past with regard to calculating damages and completing its factual investigation, as well as the related legal and regulatory analysis," says former OIG senior counsel Howard Young, with Morgan, Lewis & Bockius.

OIG notes that entering the SDP may suspend the 60-day Medicare and Medicaid overpayment reporting obligation. That's what CMS envisions in its proposed regulation on the overpayment return requirement, which requires providers to return overpayments 60 days after they are identified. There will be more guidance on OIG's website after CMS finalizes its rule.

Unlike the 1998 version, the updated SDP brings more clarity to the calculation of improper payments collected by providers — also known as damages — and drills down somewhat by the type of offense. "Our main goal and guiding light is to increase transparency in the protocol process and to give providers a clear understanding about what our expectations are and how we view these cases based on 15 years of resolving them," Maida says.

While the updated SDP has more "clarity and certainty," it will always be hampered by providers' inability to get a release from False Claims Act liability, which is outside OIG's control, says former prosecutor Robert Trusiak. That has to come from the Department of Justice, he says. This stumbling block probably explains

why self-disclosure dollars are relatively small in the scheme of things, Trusiak says. In the 15 years that the SDP has existed, Medicare and Medicaid spending averaged about $645 billion a year, but there were an average of only 53 self-disclosures a year. It would be different if DOJ "provided some type of non-binding policy statement on the factors it will consider" so a self-disclosure doesn't culminate in a false claims lawsuit (e.g., there was no criminal conduct, the provider was overpaid less than $250,000), says Trusiak, senior counsel and chief compliance officer for Kaleida Health in Buffalo, N.Y. DOJ should embrace the idea considering this is an "era of contraction" for all federal agencies.

New SDP Provides More Details

The updated SDP gets in the weeds in three areas: (1) employment of excluded providers, (2) anti-kickback and self-referral violations, and (3) false billing. "This is a much better approach than trying to guess what will be necessary," Waltz says. "OIG even provides the calculation methodology for excluded person disclosures, which has been a matter of some dispute within the provider community when the excluded individual is not the one who bills any federal programs directly."

It's easier to calculate damages when a hospital, for example, employed an excluded physician or other clinician whose services were billed directly to federal health programs, the updated SDP says. "The disclosure must include the total amounts claimed and paid by the Federal health care programs for those items or services," the updated SDP states. But it's thornier if the services provided by the excluded person, such as billers, nurses or respiratory therapists, aren't charged directly to federal health programs. In these cases, OIG has another formula. "We use the disclosing party's total costs of employment or contracting during the exclusion to estimate the value of the items and services provided by that excluded individual….This total amount should be multiplied by the disclosing party's revenue-based Federal health care program payor mix for the relevant time period."

Another area that requires damage estimates is false billing. When disclosing providers estimate damages, they must review either all claims relevant to the potential violation or "a statistically valid random sample of the claims that can be projected to the population of claims affected by the matter," the updated SDP states. Providers must include at least 100 items in the sample and use the mean point estimate to calculate damages. If they use a probe sample, for example, then "those claims may be included in the 100-item sample if statistically appropriate."

It's useful to know OIG considers 100 items a bright line, Waltz says. "The statistical guidance can be used for calculating refunds that do not result in use of the SDP, like an overpayment refund to the Medicare contractor," she says.

As for kickback and Stark violations, disclosing parties should submit an estimate of the amount paid for the goods or services associated with the violation or use sampling methodology from the false billing section. Or they can propose another "reliable methodology." Ultimately, however, the settlement will be fact-specific.

There's one thing that sticks in Waltz's craw. By continuing to insist that providers admit they violated the law or regulatory guidance, OIG puts providers between a rock and a hard place, she says. If OIG does not accept the provider into the SDP and instead refers the alleged misconduct to the Department of Justice, "the provider will be stuck with its own admission…with no wiggle room," she says.

But Maida says that some providers apply for the SDP and then balk at admitting there was a violation. "They have blanched at paying a multiplier and then they get into an argument about whether they did anything wrong," he says. "That's not the point of the protocol. If you don't think you have liability, then assume the risk and don't disclose." He hopes the updated SDP will put this to rest.

Maida adds that the updated SDP urges disclosing providers to inform OIG as early as possible if they would have a hard time paying a certain settlement amount. "There's no point getting to the end of a settlement and finding out someone has a financial issue or wants to raise a financial issue," he says.

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