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Health Care Enforcement Review And 2017 Outlook: Part 3

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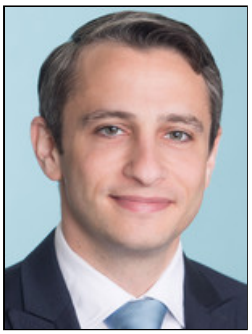
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Law360, New York (January 18, 2017, 12:37 PM EST) -- In part 1 of this four-part series, we examined the U.S. Food and Drug Administration's wide-ranging enforcement activities related to health care fraud. In part 2 we discussed 2016's major case developments in health care enforcement. Part 3 will address significant regulatory developments in this area.

While 2016 marked one of the least productive years in the history of Congress, the same cannot be said of health care enforcement and regulatory agencies. Perhaps motivated by the impending change in administration, these agencies promulgated a number of notable regulations in 2016, including:

- A U.S. Department of Justice interim final rule that significantly increases penalties under the False Claims Act, making already high-stakes litigation even higher.
- An interim final rule from the Office of Inspector General for the U.S. Department of Health and Human Services and other agencies increasing civil penalties for violations of various statutes and regulations, including the Civil Monetary Penalties Law (CMPL) and its implementing regulations.
- A final rule that addresses the OIG's expanded authority under the CMPL.
- A long-awaited final rule from the Center for Medicare and Medicaid Services concerning the "60-day rule" for returning overpayments.
- A final rule from the OIG that amends the safe harbors under the federal anti-kickback statute (AKS) and adds exceptions under the CMPL's beneficiary inducement prohibition.

Below we discuss the highlights of each rule and how we expect each to impact the enforcement environment in 2017 and beyond.

FCA and Other Civil Monetary Penalties Dramatically Increased

A 2016 interim final rule announced the DOJ's intent to increase FCA penalties by raising the minimum per-claim penalty from $5,500 to $10,781, and the maximum per-claim penalty from $11,000 to $21,563. These adjusted amounts will apply only to penalties assessed after Aug. 1, 2016, for violations occurring after Nov. 2, 2015. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which established a formula for the required increase in penalties, mandated this change. The DOJ provided a 60-day period for public comment on this interim final

rule, but the amount of the penalties undoubtedly will remain unchanged. The DOJ may, however, respond to commenters' concerns about its approach to determining the number of penalties or its decisions to actually demand these Draconian penalties.

The application of penalties typically does not arise in the context of FCA matters resolved through negotiated settlements. However, the number and amount of the penalties is relevant in litigation, as well as the basis on which they are sought (e.g., per claim, per cost report). Courts generally have considered penalties to be mandatory in the event of a final judgement of liability, which has led to challenges based on the excessive fines prohibition in the Eight Amendment to the U.S. Constitution. In one notable declined qui tam case, United States ex rel. Bunk v. Gosselin World Wide Moving NV, the relator sought penalties of $24 million but no damages. The district court thought that it lacked discretion to tailor its imposition of penalties to conform with constitutional limitations, which it found to be limited to $1.5 million under the circumstances. The Fourth Circuit disagreed and found that penalties of $24 million were not "excessive" under the Constitution, even with no proven damages and total payments to the contractor of $3.3 million. The appellate court also concluded that the district courts do have discretion to enter a lower penalty amount than the amount provided for in the statute.

The practical effect of the increase in penalties under the FCA is likely to be three-fold. First, the DOJ will have increased leverage in settlement negotiations due to the threat of even more enormous penalties if violations are ultimately proven at trial for all or part of a case. FCA defendants may therefore be more likely to settle. Second, excessive fines and other challenges are likely to resurface when the government attempts to impose substantial penalties, especially if such fines are grossly disproportionate to the proven damages. Third, courts may be more cautious in determining liability under the FCA given the severely punitive penalties that might be triggered.

In addition, the OIG and CMS published an interim final rule that adjusted penalties associated with various statutory and regulatory violations for inflation, as required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. These adjustments also give the government additional leverage in enforcement actions. For example, under the CMPL the maximum civil monetary penalty (CMP) for Stark Law violations has increased from $15,000 to $23,863 per violation, and the maximum CMP for AKS violations is now $73,588 per violation, up from $50,000.

CMPL Authorities Expanded

In December the OIG released a final rule incorporating new CMP authorities, clarifying existing authorities, and reorganizing the regulations on penalties, assessments and exclusions. The new rules took effect Jan. 6, 2017.

The following five new categories of authorities may subject a person to CMPs, assessments and/or exclusions from participation in federal health care programs:

1. Failing to grant the OIG timely access to records;
2. Ordering or prescribing while excluded from a federal health care program;
3. Making false statements, omissions, or misrepresentations in an enrollment application or similar bid or application to participate in a federal health care program;
4. Failing to report and return an overpayment; and
5. Making or using a false record or statement that is material to a false or fraudulent claim.

The final rule also revised the CMP authorities related to Medicare Advantage (MA) and Part D contracting organizations, as authorized by the Affordable Care Act. First, the new regulations expand the general liability of MA and Part D plans for the actions of their agents. Second, MA or

Part D plans may now face OIG action for:

1. Enrolling an individual without his or her prior consent;
2. Transferring an enrollee from one plan to another without his or her prior consent;
3. Transferring an enrollee solely for the purpose of earning a commission;
4. Failing to comply with marketing restrictions described in the statute or applicable implementing regulations or guidance; or
5. Employing or contracting with any person who fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual.

In response to commenters' concern that CMS also has jurisdiction to impose penalties for this same conduct, the OIG indicated that CMS and the OIG have "internal mechanisms" in place to ensure they are not simultaneously pursing CMPs for similar activities.

These authorities, coupled with increased penalties, expand the OIG's power in enforcement actions. Given that the OIG's Office of Counsel created a litigation team dedicated solely to CMP and exclusion cases in 2015, as discussed in a previous post, 2017 may bring an increase in cases initiated by the OIG.

60-Day Rule Regulations Provided Long-Awaited Guidance

Health care providers finally have some clarity as to the application, under Medicare Parts A and B, of the "60-day rule" for the reporting and refunding of "identified overpayments." The ACA requires a provider or supplier to report and return an "overpayment" within 60 days of "identification." The ACA defined an "overpayment" as "any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled under such title." Though the proposed rule was issued in February 2012, it created enormous uncertainty around key issues and provoked substantial comments. CMS issued the final rule four years later, on Feb. 12, 2016. It became effective as of March 14, 2016.

Certain key provisions of the final rule and differences between the proposed and final rules are notable. First, CMS clarified that the term "identified overpayment" requires "identification" of the overpayment and "quantification" of the amount. This clarification is key because the 60-day clock does not begin to run until there is an "identified overpayment." The fact that quantification is required allows the provider more time. Second, CMS declared that the "identification" is triggered when a provider "has, or should have through the exercise of reasonable diligence," determined that it has received an overpayment.

In CMS's view, "reasonable diligence" requires both proactive compliance measures (conducted in good faith by qualified individuals) to monitor for potential overpayments and timely, good-faith investigation into "credible information" of a potential overpayment. CMS further opined that absent "extraordinary circumstances," the investigation is not expected to exceed six months. Third, as to the quantification, the final rule makes clear that the overpayment amount may be determined by statistical sampling and extrapolation, so long as the methodology is disclosed. Fourth, under enormous pressure from commenters, CMS reduced the look-back period to six years, instead of the proposed 10 years. For additional analysis of the final rule, see our previous post.

On the enforcement side, failure to report and return a known overpayment within 60 days or when a cost report is due constitutes a violation of the CMPL, as discussed above. The CMPL violation is subject to a penalty of $10,000 per item or service ($10,874, after the inflation adjustment described in the September 2016 interim final rule increasing CMPs). The risk is magnified under the FCA, which now defines "obligation" as the "retention of an overpayment." However, once there is an "obligation," FCA liability does not arise unless a provider "knowingly

conceals or knowingly and improperly avoids or decreases an obligation" to repay the United States.

Although relators routinely allege a violation of the FCA for a failure to report and return an overpayment, these allegations are typically derivative and duplicative of allegations under the false claims and/or false statement allegations. FCA case law thus has failed to shed light on the FCA standard of liability — knowing concealment or knowing and improper avoidance — and no decisions have addressed the relatively new final rule. In August 2015, United States ex rel. Kane (involving New York Medicaid payments to hospitals), the U.S. District Court for the Southern District of New York denied a motion to dismiss and, with only the guidance from the statute and proposed rule, decided that the clock is triggered when a provider is "on notice of a set of claims likely to contain numerous overpayments." The parties resolved this matter in August 2016, with the hospitals paying $2.95 million to resolve state and federal FCA allegations.

In 2017 and beyond, providers should consider taking one or more of the following steps consistent with the final rule to avoid or mitigate potential liabilities:

- Implement "proactive compliance measures," suitable for the provider and risks specific to it, to avoid allegations that it "should have known" about an alleged overpayment;
- Promptly evaluate any information (internal data, internal reports or complaints, or external sources) that might be "credible" information of an overpayment and establish procedures to determine, and document, whether information is verified as "creditable" or not;
- In the event of credible information, establish a process to verify the overpayment and quantify that meets the "reasonably diligent" standard in terms of both timing and substance;
- If an investigation does or will take more than 6 months, determine the best course of action to document the process and/or communicate with Medicare or Medicaid to mitigate vulnerability to an allegation of "knowing concealment" or "knowing and improper avoidance" of the repayment obligation;
- Prepare to "report and refund" by documenting internally the work performed to verify and quantify the overpayment; and
- Decide, based on a variety of factors, to whom the overpayment should be reported and refunded, and what information to provide with that refund.

New Beneficiary Inducement Exceptions and AKS Safe Harbor Amendments

Finally, the OIG published a final rule in December 2016 implementing changes to the AKS safe harbors and the beneficiary inducement prohibition, which is part of the CMPL regulations. The final rule made few significant changes to the proposed amendments to the safe harbors (and thus we refer you to our previous advisory on the proposed rule for additional details). But it did provide important guidance on the new exceptions to the beneficiary inducement prohibition, which forbids the offering of "remuneration" to a Medicare or Medicaid beneficiary if the offeror knows or should know it is likely to influence the selection of particular providers, practitioners or suppliers.

The final rule amends the definition of "remuneration" by codifying five statutory exceptions, which we examined in a prior post. Given that these statutory exceptions have existed for many years without the OIG saying much about how it interprets them, the health care industry eagerly anticipated publication of the final rule. While not clear (or helpful!) in all respects, it is at least a good start. Below we discuss the two exceptions that received the most attention in the final rule.

Remuneration that Promotes Access to Care and Poses a Low Risk of Harm

The OIG codified an exception for remuneration that "promotes access to care and poses a low risk of harm to patients and federal health care programs," which was added by the ACA. While the OIG has considered this exception in a handful of advisory opinions, it has provided little substantive guidance since the ACA's passage in 2010. Based on comments received following the proposed rule, the OIG defined the following key concepts associated with this exception:

- "Care" includes any items or services provided to a Medicare or Medicaid beneficiary, and is not limited only to medically necessary care.
- An arrangement "promotes access to care" only if it "improves a particular beneficiary's ability to obtain" care, but the OIG drew the line at remuneration that rewards patient adherence.
- Remuneration "poses a low risk of harm" if the items or services: (1) are unlikely to interfere with, or skew, clinical decision making; (2) are unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) do not raise patient safety or quality of care concerns.

Coupons, Rebates and Other Retailer Reward Programs

The final rule also codified another exception included in the ACA, which permits a retailer (i.e., an entity that sells items directly to consumers) to offer or transfer coupons, rebates or other rewards for free or less than fair market value if the items or services are available on equal terms to the general public and are not tied to the provision of other items or services reimbursed in whole or in part by Medicare or Medicaid. According to the OIG, the retailer rewards exception creates a pathway for retailers to include Medicare and Medicaid beneficiaries in their rewards programs without violating the beneficiary inducement provisions of the CMP.

Retailers include independent or small pharmacies, online retailers and entities that sell a single category of items, but not individuals or entities that primarily provide services (e.g., physicians or hospitals). The OIG explicitly stated that manufacturers are not considered "retailers" for purposes of this exception.

The items or services must be offered or transferred on equal terms to the public, regardless of health insurance status. To meet this requirement, the general public must have the same access to, and use of, the retailer reward as the retailer's insured customer base, but the OIG clarified that a retailer may implement an enrollment process to qualify for the reward.

Finally, the OIG clarified that the reward may not take the form of discounts specific to Medicare or Medicaid reimbursable items or services, but it can take the form of a discount that can be used on anything in the store, including Medicare- or Medicaid-covered items or services.

The final rule became effective on Jan. 7, 2017. While the health care industry certainly welcomes the OIG's official interpretation of these exceptions, it is cold comfort in some respects. The OIG mentioned numerous times throughout the final rule that compliance with an exception to the beneficiary inducement prohibition does not guarantee that the arrangement will not trigger scrutiny under the AKS. While it seems unlikely that an arrangement that meets an exception could violate the AKS, it is not impossible.

Conclusion

Recent political developments have cast some ambiguity over the fate of some of these and other agency rules. As we discussed last month, Congress has signaled its intent to closely scrutinize the rules adopted in the waning days of the Obama administration under the authority of the Congressional Review Act, which gives Congress the authority to adopt joint "disapproval resolutions" to effectively overturn final regulations adopted within 60 days prior to the present Congress' adjournment. However, these regulations may survive given that health care fraud and abuse is an issue that typically garners bipartisan support.

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