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Watching out for America's health

an interview with Mike Joyce

Vice President, Chief Auditor
& Compliance Officer
Blue Cross Blue Shield Association
Chicago

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by Deanna Mool, JD, CHC and Tyler Robinson, JD

How to self-disclose and re-tool compliance at the same time

» A provider must address government overpayments by refunding the claim or by using the Self-Disclosure Protocol (SDP).
» The board decision to file a SDP should be based upon the facts, such as the scope and duration of the issue.
» A self-disclosure should not be filed until the conduct causing the self-disclosure is resolved.
» The SDP requires the provider to document corrective actions, which should include a review of compliance efforts of the problematic program.
» Finding out why a problem happened and how to assure it doesn't happen again is imperative for a facility engaged in the SDP.

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Encountering a government overpayment is inevitable for healthcare providers. Government agencies that fund healthcare expect that all identified overpayments will be refunded in a timely and complete manner. It is an axiom, though, that not all government overpayments are intentional or the result of a fraudulent scheme.

Overpayments can result from unintentional acts, such as submitting claims for government reimbursement that are later deemed to be medically unnecessary, inadvertent coding errors, improperly credentialed providers, or impermissible referrals under the Stark Law.[1] Even in the presence of an effective compliance program, a billing audit may discover a coding error that has been occurring, unbeknownst to the provider, for years. Whether the overpayment was intentional or inadvertent, federal law requires reasonable diligence within which the healthcare provider must identify and quantify the overpayment. Once the overpayment is identified and quantified, the healthcare provider has a number of legal options for reporting and repayment, including claims adjustments and government self-disclosures.


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The foregoing discussion presents facts and circumstances that may warrant disclosure under the U.S. Department of Health and Human Services (DHHS), Office of Inspector General (OIG) Self-Disclosure Protocol (SDP), which is one of the available government self-disclosures. There is more than one type of self-disclosure to the federal DHHS. For a billing error, the most likely disclosure would be the SDP to the OIG. The SDP is available to those providers who make a determination that they have potentially violated federal criminal, civil, or administrative laws for which Civil Monetary Penalty (CMP) liability is authorized. Determination of whether use of the SDP is appropriate involves an analysis of the CMP liability and whether the violations of federal laws occurred with actual

knowledge, reckless disregard, or deliberate indifference. That is, violation of a federal law, by itself, does not conclude the analysis of whether the SDP is appropriate. Instead, the provider must have violated a federal law with the requisite knowledge that gives rise to CMP liability.

It should be noted that prior to disclosure, the SDP requires that the provider certify that the disclosed conduct has ended or that corrective action will be taken within 90 days of submission of the SDP. Further, OIG expects that all other necessary corrective action should be complete and effective at the time of the disclosure.

Investigation team

The government overpayment process must be managed as a team effort, both within the organization and, in many cases, with trusted external advisors. You may find the core team to have few members, particularly in smaller providers, which consists largely of senior management. Outside legal counsel and retained consultants are often added to the core team to quickly identify the scope and breadth of the applicable overpayment issue(s) and advise the provider on a number of possible next steps and legal options, including the retention of third-party experts for regulatory or billing opinions and, if necessary, sampling and quantification of the government overpayment, claims adjustment/reconciliation, and government self-disclosure.

Within larger providers, more internal staff resources may be available to devote to these efforts. If so, providers should have written policies and procedures detailing the roles that each member of the investigation team is responsible for leading and, in some cases, delegating to downstream members of the organization. Larger providers may determine that the use of outside legal counsel provides attorney-client privilege benefits. As a general proposition, in-house counsel may not be able to provide sufficient attorney-client privilege to prevent critical details of the investigation from disclosure to third parties, particularly in scenarios where the in-house counsel also serves as the provider's internal compliance officer. That is, in the circumstance of a dual-role in-house counsel, it may not be clear in which capacity he/she is operating within any given set of circumstances, thereby eliminating the presumption that the communication was in the context of anticipated litigation. This is one of the many reasons that the Compliance and Legal functions should be separate. In addition, this situation demonstrates why outside counsel is also a recommended component of most investigation teams.

Simple claims adjustment may be insufficient

Although federal law pertaining to overpayments does not set forth a specific threshold of when a claim adjustment is appropriate versus a government self-disclosure, a good place to start the analysis is to evaluate whether the government overpayment was of limited scope and duration. There is no absolute rule on the duration or scope of the government overpayment, and each matter should be independently evaluated based upon the applicable facts and circumstances. For instance, if a provider identifies a billing error pertaining to a single type of service that results from a recent software upgrade in its Billing Office, it may be sufficient to simply report and return the overpayment to the appropriate federal agency. If the billing error was widespread and occurred over an extended length of time, it might be equally appropriate to self-disclose to the government utilizing the OIG SDP.

Although duration and scope of the government overpayment are certainly relevant to the analysis, there are additional complex legal analyses that are required to

determine whether certain federal liabilities exist, such as the Civil Monetary Penalty Law[2] or the False Claims Act,[3] which would warrant disclosure to the OIG and/or to the Department of Justice.

For a billing issue, your SDP team needs to determine whether the issue warrants a request to involve the Department of Justice (DOJ) along with the OIG. Participation in the SDP, by itself, does not stop the DOJ from pursuing False Claims Act (FCA) liability against the provider. The SDP contemplates the OIG consulting with the DOJ on civil and criminal matters. Such a consultation, however, does not guarantee the DOJ will become involved in the SDP. DOJ may, on its own accord, join the SDP and provide an additional release in the settlement agreement relating to the FCA. Depending on the issue, the SDP team may request that CMS involve the DOJ. Such a request is made through the assigned OIG special agent for purposes of attempting to extinguish liability under the FCA.

As one can easily see, there are no absolutes and, although there exists a degree of provider discretion, the government expects prompt and complete reporting and repayment in compliance with applicable federal law.

Some providers may be able to opt for simply adjusting claims; however, under new federal laws, simply adjusting claims is insufficient in almost all instances of government overpayments. Even in minor overpayments, the policies of the fiscal intermediary must be consulted to determine whether there is a requirement that the rational for the refund will be provided. Some providers, particularly those who are a sub-division of state/local government, may need to self-disclose, rather than refund, in order to fulfill ethical or state/local law obligations.

The board decision to self-disclose

Typically, the decision to self-disclose is a board-level decision, because of the potential exposure to the provider in both fines and penalties. In addition, a final settlement is disclosed to the public via press release and the settling agency's website. The federal agencies see such public discourse as both a deterrent and as an opportunity to demonstrate the success of the SDP. With respect to the former, OIG's general practice is to require a minimum multiplier of 1.5 times the single damage amount if the disclosed conduct violates the CMP. It should be noted that there is no maximum multiplier, although a range of 2.0 to 4.0 times the single damage amount is typically applied. Depending on the facts and circumstances of the disclosed subject matter, however, OIG may determine that a higher multiplier is appropriate. It is very common to see at least a 2.0 times multiplier applied to the single damage amount in SDPs.

The investigating group should organize the information collected in their internal investigation and present the same in a concise, presentation-style meeting to the board during a closed session. It is not uncommon for the investigating group to encounter questions pertaining to the individual liability of board members. Although the response to such a question varies significantly based on a variety of factors, including the ownership of the hospital, providers should be generally aware of the Yates Memo, which highlighted the federal government's focus on holding individual wrongdoers accountable in the course of corporate investigations. (The Yates Memo, a memorandum addressing "Individual Accountability for Corporate Wrongdoing," was issued by Deputy Attorney General Sally Yates to all Department of Justice components and United States Attorney's Offices on September 9, 2015.) Notwithstanding the tenor

of the investigation, the board presentation should be one of transparency and contain an analysis of the risks and benefits of each available legal option.

Protected investigation into the "why"

In the event the board votes to proceed with the submission of a disclosure pursuant to the SDP, the first step is to verify that the conduct subject to the disclosure has ceased. If the relevant conduct has not ceased, the provider should take immediate action to remedy the conduct at issue. Once the conduct has ceased, the provider should undertake an investigation to determine why the issue occurred. The investigation often takes on a form akin to a root cause analysis, which, if performed under the protection of either the attorney-client or attorney-consultant privilege, has a strong presumption of privilege from third parties.

In the context of the investigation, and if outside legal counsel is involved, it is important to provide Upjohn warnings to ensure that downstream employees being interviewed (or otherwise providing communications to the provider or its legal counsel) understand that the attorney-client privilege is possessed and can be waived only by the provider, not the employee. An Upjohn warning is a written communication that a provider's employees will sign before being interviewed by outside counsel. The warning makes clear that the attorney-client privilege associated with the interview is a privilege held by the provider, not the employee, and can be waived by the provider without notice or consent of the employee. The purpose of the warning is to make clear that the provider's counsel represents the provider and not the individual employee. For a variety of reasons, there are times when the provider wishes to waive the attorney-client privilege in the future in an effort to exemplify transparency and cooperation with the government in hopes for an expeditious and reasonable resolution.

Submission of the SDP

The disclosing provider must (a) explicitly identify the federal criminal, civil, or administrative laws that were potentially violated; (b) institute corrective action and end the disclosed conduct within 90 days of submission to the OIG; (c) complete an investigation and damages audit within three months of acceptance into the SDP; and (d) tender a written self-disclosure to the OIG. As it relates to the actual, written self-disclosure, the provider must follow the SDP. Information included in the written SDP document generally includes the following:

- General background information about the disclosing provider;
- Identification of the laws that are potentially violated and the healthcare programs affected by the disclosed conduct;
- Estimate of damages; and
- Description of corrective action.

OIG expects disclosing parties to disclose in good faith and to possess a willingness to resolve all liability within the CMP's six-year statute of limitations. As such, the look-back period for the SDP is six years from the time at which any claim, request for payment, or other occurrence took place that is part of the violation being disclosed. In submitting a SDP to OIG, the disclosing provider must be ready to own the conduct given the fact that, if the SDP fails, the OIG could pursue an administrative action dating back six years from the date of submission.

Describing your corrective action through compliance

As part of the SDP, the provider discloses all corrective actions. One of those corrective actions should be a substantive review of the

governing documents, procedures, and training that led to the issue. It is also advisable to review the provider's compliance processes. Most providers have designated someone to be in charge of "compliance," but not every provider has a given the compliance officer the appropriate title and authority to solve compliance issues. Further, the provider might not have invested in fully training the compliance officer, granted the compliance officer access to legal advice, or stayed abreast of recent changes to health care laws.

Most providers do not intentionally fail in compliance efforts, but they may fail to prioritize compliance within their organizational structure. It is difficult to appreciate the return on investment in compliance activities until there is an issue. Although this failure may be understandable in the constantly changing healthcare sector, it is because of this constant change that policies, training, and education become key to a provider's success. Providers generally accept the notion of preventive care for patients, but some providers may not perceive the beneficial investment in preventive care for the provider through a robust compliance program.

Although the initial SDP may only include brief statements on how the provider is undertaking corrective actions, subsequent conversations with the government should include more substantive descriptions of the provider's corrective actions. If staff has changed, the bylaws have been modified, procedures have been updated, or the process is on-going, these changes should be part of the dialogue with OIG and any other federal or state agencies involved in the SDP. Further, these remedial efforts need to be communicated and coordinated with the team advising the provider on the SDP. For example, if staff changes occur in the Medical Records department or Billing Office, providers should notify their outside advisors—particularly if the provider has engaged outside counsel—because they are not present at the facility on a daily basis.

Thus, while the SDP is working its way through the expedited process, the provider should be focused on improving its compliance program. Many times the need for an SDP is symbolic of systemic problems within the facility. For example, if a provider is billing prior to being appropriately credentialed, fault does not typically lie within one area. You may find that the hiring was done by a department that failed to communicate with Human Resources, no one checked that the credentialing application was properly filled out, the credentialing process was never started, no internal audit occurred of the new provider's bills, or the Billing Office continually billed charges with no review. Any or all of these problems can be identified and remedied while the SDP process is ongoing, through a dual-approach of satisfying the SDP requirements while continuing to develop and implement improvements to the provider's compliance program. Many times, the genesis of the disclosed subject matter was a lack of procedures, training, and communication. Further, a lack of senior management and board training and/or involvement in the compliance process can exacerbate these issues.

In order to determine whether and how the provider's processes are failing, a compliance assessment is recommended to become part of the SDP. As part of the SDP, the provider will represent that it operates under an effective compliance program. A full review of the compliance program in areas affected by the SDP gives the facility a reasonable basis for making such a representation to the government.

Assessing the compliance program for purposes of an SDP frequently becomes a joint effort between consultants and legal counsel. In assessing the compliance program, key

program staff are interviewed to determine their perception of compliance efforts, their implementation of various policies, and the specific needs of each program. Based upon the results of these interviews, a set of action steps is created for the provider to undertake. Depending on the nature of the provider's issues, these action steps may include re-drafting of policies, amending the provider's risk assessment to include new findings, or further training. All of these compliance efforts should be documented for potential use in the SDP.

Conclusion

No facility relishes the notion of undertaking the SDP process. The SDP investigation and submission process must be carefully navigated so as to protect the attorney-client privilege and to have full board involvement in light of the significant penalties and likely public disclosure of any settlement. Further, the provider should carefully select those who will represent the provider in negotiations with the government to ensure complete, transparent cooperation. The SDP process can seem overwhelming, but when coupled with a serious look at the provider's compliance program, the process oftentimes results in a stronger facility that is better prepared to provide services in a more efficient, compliant manner.

1. 42 U.S.C. §1395nn.
2. 42 U.S.C. §1320a-7a.
3. 31 U.S.C. §3729.