Human Resources Administration
Department of Social Services

Investigation, Revenue, and Enforcement Administration

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Kenneth D. Kraft
Office of the Inspector General
Dep't of Health & Human Services
Attn: OIG-1301-N, Room 5541B
Cohen Bldg, 330 Independent Ave. SW
Washington, D.C. 20201

RE: Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol, Department of Health and Human Services, Federal Register Docket Number OIG-1301-N

Dear Mr. Kraft:

The New York City Human Resources Administration (HRA) is pleased to submit these comments on the U.S. Department of Health and Human Services (HHS) Office of Inspector General's Provider Self-Disclosure Protocol (OIG SDP). HRA appreciates the call for comments on this revolutionary, effective, and instrumental program.

HRA administers Medicaid for over three million New Yorkers at a cost of over $35 billion annually. The responsibility for protecting the integrity of the programs the Agency administers falls within the investigate arm of HRA- the Investigation, Revenue and Enforcement Administration (IREA). Through IREA we have pioneered a range of investigative practices and techniques that are models in the field. We are also in the process of developing the first self-disclosure program for social services' beneficiaries.

These comments are submitted in the hope that they will add to the continued success of the OIG SDP and potentially increase its effectiveness and utilization. We believe there are ten elements of an effective disclosure program, which are explained below along with suggestions for specific changes to the current OIG SDP.

Presently, in order to utilize the OIG SDP, the provider must: (1) make an effective disclosure, (2) include basic information within the submission, and (3) include substantive information in the disclosure. The OIG will then do an internal investigation and comprehensive assessment of the submission. After the OIG performs such assessment, the provider must assess the monetary impact of the matter. The assessment must be performed in tandem with the investigation, and the final number is subject to verification by the OIG. After the self-assessment, the provider must certify

that the report is true and based on a good faith effort. Finally, the OIG will verify all of the information and will not accept payment until after the verification.[1]

Between October 1, 2011 and March 31, 2012 OIG collected $15.4 million in receivables from the Protocol.[2] That number is part of the $1.2 billion OIG expects to collect in total receivables during that period of time.[3] The New York State Office of Medicaid Inspector General (OMIG) administers a provider self-disclosure program, which collected recovered approximately $13.5 million in 2010.[4]

I. Elements of an Effective Disclosure Program

Based upon our experience and consultation with the compliance community, we believe the following ten elements compromise an effective disclosure program. The elements are not ranked in order of importance, but, instead, as components that should be weighted and considered. Some of these elements are already incorporated in the SDP.

1. Clear and Easily Accessible Instructions

In order to make an initial determination regarding disclosure, providers must be able to find clear instructions to the Self-Disclosure Protocol. Although the disclosure itself will involve attorneys and other professionals, providers ultimately make the initial decisions. Programs similar to HHS SDP utilize online guides, such as the New York State OMIG.[5] New York State goes one step further and enumerates specific benefits to utilizing its program that you may want to consider, including: (1) forgiveness or reduction of interest payments, (2) extended repayment terms, (3) waiver of penalties and/or sanctions, (4) recognition of the effectiveness of the provider's compliance program, (5) a decrease in the likelihood of imposition of an OMIG Corporate Integrity Program, and (6) possible preclusion of subsequently filed New York State False Claims Act qui tam actions based on the disclosed matters.[6]

2. Forms Available Online

The SDP Submission Guidelines[7] indicate OIG prefers streamlined information. There are specific requests for thoroughness in information, and we believe forms are an efficient way to

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[1] 63 Fed. Reg. 58403
[2] Office of Inspector General, Semiannual Report to Congress, Page III-20, III-21.
[3] *Id.* at page i.
[4] New York State Office of Medicaid Inspector General, Annual Report 2010 at 4. http://www.omig.ny.gov/data/images/stories/annual_report/annual_report_2010.pdf. (Please note this program is mandatory).
[5] New York State Office of Medicaid Inspector General, Provider Self Disclosure Guidance. http://www.omig.state.ny.us/data/images/stories/self_disclosure/omig_provider_self_disclosure_guidance.pdf.
[6] STATE OF N.Y. OFFICE OF THE MEDICAID INSPECTOR GEN., SELF-DISCLOSURE GUIDANCE (Mar. 12, 2009).
[7] Fed. Reg. 58401 (Section III. Voluntary Disclosure Submission)

submit information. This allows the provider to easily input all required information/documents and give the OIG a standardized product. While certain disclosures will include more information than others, the form should be made for basic information, and allow attachments for additional information.

3. Definable Path to Resolution

We believe that addressing some of the "uncertainties" in the program could assist in increased participation by providers. When offering a disclosure, that provider is opening sensitive internal information to an agency with considerable regulatory and legal authority. In order to encourage more providers to disclose using the SDP, there should be a level of predictability inherent in their participation.

4. Defined Role and Protections for Professionals and Advisors

Often a provider will make a disclosure once the compliance program indicates there is an issue. A disclosure signals an effective compliance program. A disclosure is a complicated and onerous matter, involving many working parts and professionals. Providers and health-related professionals would benefit from guidance regarding where each component fits. One form could be a description of how lawyers, consultants, or information-technology specialists can assist in the process. To the extent it is possible, the guidance should explain how the disclosing entity can protect privileged materials, while providing necessary information.

5. Transparency

Transparency is a vital component of any governmental program, as it instills trust and understanding in those that deal with government agencies. The OIG should be open regarding how matters will be resolved in order to facilitate those that come forward and encourage those that are unsure that going forward is the correct answer.

6. Recognition of Good Faith Efforts of Providers and Organizations

In general, self-disclosing a violation of law symbolizes that a party's compliance program is working effectively. Recognition of compliance efforts is an important element in facilitating good will in the health care compliance field. Some providers may feel uneasy about coming forward for fear the compliance program will not be recognized or the disclosure will be treated as an investigation as opposed to a collaborative process. Some disclosure programs have affirmatively stated a disclosure is evidence of an effective compliance program and believe this is a concept that deserves consideration.[8]

[8] *See* Jean Wright Veilleux, Catching Flies with Vinegar: A Critique of the Centers of Medicare and Medicaid Self-Disclosure Program, 22 HEALTH MATRIX 169, 214 (2012) (describing the New York OMIG disclosure program and incentives).

7. Effective Communication

Communication is an essential element of any self-disclosure program. In order to facilitate effective communication, the government entity must make it clear who is working with the disclosing party and to what extent. If an attorney is assigned to work with the party, it is helpful to understand how the assignment is made, and if that assignment is exclusive. In other words, will the party be working with that attorney throughout the process, or will other attorneys and/or supervisors be involved along the way? Answers to these questions should be included in every self-disclosure program.

8. Clear Explanation of How to Deal With Ongoing Implications of Past Conduct

During the course of the self-disclosure process, providers will identify prior reports, claims, and certifications that may now be inaccurate based on the focus of their self-disclosure. Providers should be confident the OIG SDP focuses on the claim at hand. Thus, the OIG should develop a protocol that discusses how providers should treat prior certifications. If the focus of the OIG SDP is to disclose the information discovered and reported, then providers should be confident that the OIG SDP focuses only on the claim at hand—this should not apply for public health and safety violations.

9. Support for Compliance Efforts

OIG should make a statement regarding how disclosed activity fits into the compliance program. Although Corporate Integrity Agreements (CIAs) have become less common, OIG should not shy away from stating that CIAs are only implemented in extreme cases. Making a self-disclosure is an indicator of an already-functioning compliance program, and the OIG would be prudent to state how disclosure will impact or improve that compliance program.

10. Clear Payment Terms

Many successful self-disclosure programs affirmatively advertise payment terms and options. For example, the Department of Justice takes into account a disclosing party's ability to pay after a full financial disclosure. Although financial disclosures are weighty requests, the option of various payment terms is something some disclosing parties may choose to take advantage of. Payment terms may range from reduced payments to payment plans, depending on the financial situation of the disclosing party.

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II. Compilation of Specific Suggestions for Office of Inspector General's Provider Self-Disclosure Protocol

1. Consolidate Open Letters and Self-Disclosure Protocol

Currently, OIG has links to the 1998 Protocol, as published in the Federal Register, on its website, along with links to the three published open letters. While these things are helpful, it might be prudent for the OIG to put up a comprehensive "guide" that providers can use, as the federal register can be dense and difficult to navigate. Furthermore, the separately published open letters require users to look in multiple places to ascertain the rules and regulations of the program. In order to simplify the SDP and make instructions clear, OIG should consolidate all documents into one comprehensive guide. Consolidation will be especially helpful for those entities considering disclosure that have yet to retain knowledgeable players.

2. Indicate How a Disclosure Affects the 60-day Repayment Period

When a provider identifies a STARK violation that implicates an overpayment, there is a 60-day period of government repayment.[9] An affirmative statement from OIG indicating that a disclosure under the SDP will toll the 60-day period would encourage providers to utilize the Protocol.[10] Furthermore, it will prevent premature repayment.

3. Clear Statement of the Protocol's Intent

A preamble stating the intent under which the protocol will operate could alleviate preliminary concerns from providers and set the tone before a disclosure comes in the door.

4. OIG Should Indicate a Definable Path to Resolution

First, OIG should publish all disclosures after a settlement has been reached. Although there are "selected settlements" publicized on the website, the short synopsis does not offer guidance to those providers considering disclosure. Although there is an understandable desire from providers to not want settlements made public, with names and public information redacted, it should protect the disclosing parties and serve as examples to future providers. No two disclosures will be alike, but the more facts that are included, the more a provider can decide if the disclosure process is the correct venue. Publicizing more disclosure could also aid compliance officers in encouraging corporations to disclose.

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[9] PPACA § 6402(a), 124 Stat. at 755.

[10] The Center for Medicaid/Medicare Services has made this affirmative statement in their self-disclosure program. *CMS Voluntary Self-Referral Disclosure Protocol*, CMS.gov (revised May 6, 2011), www.cms.gov/PhysiciansSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

Second, OIG should commit to timelines in terms of resolution. In a 2008 Open Letter to Health Care Providers, Inspector General Levinson asked that providers complete the investigation and assessment of damages within three months of acceptance into the SDP.[11] This request has pushed the SDP in the correct direction, adding timeliness to the process. To further that goal, OIG should indicate when a provider will get accepted or rejected from the SDP and how long the OIG's resolution process will last.

Third, parties should know who within the OIG is handling each case. The OIG should post organizational charts of those handling SDP cases online. The organization charts should be broken down by geographic area or some other reference so that local attorneys can identify who will be their OIG contacts.

5. OIG Should Advertise Flexible Payment Terms and Options

Section VII of the SDP currently does not touch upon a provider's ability to pay. Much like the Department of Justice, OIG should affirmatively state that the provider's ability to pay, and if a public entity, the impact on the organization's mission will be taken into account and should specify the process for doing so. Moreover, the OIG should opine and provide guidance on the impact and convergence of Section 6402 of the Affordable Care Act. Section 6402 requires providers disclose any overpayment to the HHS Centers for Medicare and Medicaid Services (CMS). The OIG should clarify when and whether providers must disclose to CMS only, or whether reporting something to CMS is sufficient to invoke the OIG SDP.

6. The Self-Disclosure Protocol Should Treat All Disclosing Parties Equally

OIG should announce an affirmative policy of equal treatment when parties come forward to disclose inappropriate or fraudulent activity. This equal treatment should be based on the premise that all parties coming forward are equal and only contributing factors such as good faith and cooperation should then mitigate damages or settlements. This policy must be affirmatively stated in light of the United States Supreme Court's interpretation of certain fraud and abuse laws. Specifically, the Court has ruled that under the False Claims Act a state is not a "person" for purposes of liability, but a City is as a person.[12] This difference is made in the context of litigation. OIG is not bound by such a distinction when a voluntary disclosure is involved outside the court system.

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[11] 2008 Open Letter.

[12] Vermont Agency of Natural Resources v. United States ex rel. Stevens, 529 U.S. 765 (2000) (stating a state is not a person for purposes of the False Claims Act and therefore a qui tam relator cannot bring a suit against a state agency); Cook County v. United States ex rel. Chandler, 538 U.S. 110 (2003) (holding that a City is subject to False Claims Act liability, thus a qui tam relator may bring an action).

Should there be any questions or concerns regarding the above comments, please do not hesitate to contact me at 212-274-6085 or via written correspondence. I would like to express thanks to OIG for calling for comments on this important Program.

Respectfully,

/s/ Jim Sheehan

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cc: Robert Doar, *Commissioner*