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OIG Self-Disclosure Protocol 2.0: Evolution Continues with Online Application [Ober|Kaler]

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The OIG continued its Self-Disclosure Protocol (SDP) evolution this year when it announced that its voluntary SDP application was available online at the Self-Disclosure Protocol home page. The new online application is the second SDP update from the OIG this year and follows the April 2013 revision to the OIG Self-Disclosure Protocol. This article provides a quick summary of the online application and revisits noteworthy innovations to the 2013 SDP.

The online application is an alternative to submitting voluntary self disclosures by mail. The application breaks up the submission into five data components and allows users to save and continue their entries during the submission process.

The OIG has issued several Open Letters that modified the original 1998 SDP, but the April 2013 revision is the SDP's first wholesale change. The contents of these 2006 [PDF], 2008 [PDF] and 2009 [PDF] Open Letters are widely known and are largely incorporated in the 2013 SDP. The 2013 SDP is also written less formally, making it easier to understand than the 1998 SDP, particularly in its lengthy description of the data submissions required for a voluntary self-disclosure.

The 2013 SDP includes a number of noteworthy clarifications. It clarifies that the SDP is not limited to only traditional Medicare suppliers and providers like health care facilities and physicians, but is available for any party's conduct, like a pharmaceutical company or medical device manufacturer, that could trigger the OIG's CMP authority.

The 2013 SDP also clarifies that disclosing parties need only explain that a "potential violation" exists. From a pragmatic perspective, any voluntary self-disclosure should include conduct only where a violation exists. Where a colorable reason exists that the conduct did not implicate the OIG's CMP authority, the OIG would prefer that conduct not be disclosed.

It is also worth reminding potential "disclosing parties" of the changes to the statute of limitations and the need to have taken corrective actions, although these now-published changes are consistent with the OIG's evolving position with the SDP. The 2013 SDP explains that a disclosing party waives statute of limitations, laches and other similar defenses to any administrative action filed subsequently by the OIG in relation to the disclosed conduct. The OIG also expects self-disclosures to occur at the end of the disclosed conduct. Disclosing parties should end the conduct or be within 90 days of terminating a potentially violative relationship before making a voluntary self-disclosure.