

The Do's and Don'ts and Government Trends of Voluntary Self-Disclosures

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"There can be no doubt but that the statutes . . . of Medicare and Medicaid are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most torturous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process of making any solid grasp of the matters addressed merely a passing phase."

Rehab. Ass'n of Virginia, Inc. v. Kozlowski, 42 F.3d 1444 (4th Cir. 1994)

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Agenda

- Provider Overpayment Obligations
- Government Self-Disclosure Protocols
- Decision-Making Process of Disclosures
- Enforcement and Self-Disclosure Settlement Trends
- Do's and Don'ts of Voluntary Self-Disclosures
- Post-Disclosure Readiness



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Overpayments: What are Your Legal Obligations?

- Report and return the overpayment to the Secretary the State, an intermediary, carrier, or contractor, as appropriate; and
- Notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment

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Suspected Overpayment; Now What?

1. Investigate all credible information
 - all deliberate speed to make overpayment determination
 - reasonable diligence to ID determined overpayments
 - Timeframe: 6 months (+60 days to report and refund)



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Suspected Overpayment; Now What?

2. Calculate and submit the refund with 60 days of identified and known overpayments (or the date any corresponding cost report is due, if applicable)
 - Failure to repay creates "reverse" false claims act risk
 - May use statistical sampling, extrapolation or other methodology so long as its accurate and reliable
 - Lookback period is generally 6 years from date of overpayment identification
 - No de minimis exceptions

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Avenues to Refund Overpayments

1. Reopen/reprocess claims if within claims reopening period
 2. Credit balance refund/filing
 3. Voluntary refund process or other process established by your MAC
 4. OIG's Self-Disclosure Protocol (SDP)
 5. CMS' Self-Referral Disclosure Protocol (SRDP)
- NOTE: DOJ or MFCU reporting does not satisfy reporting/refund obligations

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When to Use the Self-Disclosure Protocols

- Medicaid and/or Medicare Part A or B claims at issue
- Stark Law or Anti-Kickback Statute violation at play
- Beyond the claims reopening process
- Significant amount/too large to run as a credit balance within 60 days
- Cannot afford to pay back in full



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CMS's Self-Referral Disclosure Protocol (SRDP)

- For actual or potential Stark Law violations only
 - Prohibited physician financial relationship
 - Designated health services referrals
- Open to all provider and supplier types
- Tolls the 60 day repayment obligation
- Abbreviated protocol for certain Stark Law violations
- Long process: 3+ years to adjudicate an SRDP

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OIG's Self-Disclosure Protocol (SDP)

- For actual or potential violations of any federal criminal, civil or administrative law for which CMPs are authorized
- For all providers and suppliers subject to CMPs
- Used for conduct that implicates Stark Law and AKS
- SDP must be accepted by OIG for self-disclosure credit
- Tolls the 60 day repayment obligation
- Minimum mandatory settlement amounts
- Presumption of 1.5x damages (vs. treble) and no CIA
- Adjudication usually within one year

Pros and Cons of Self-Disclosures

Pros	Cons
Settlement amount likely lower than full repayment obligation and lower repayment multiplier	Costly and time-consuming process (OIG faster than CMS)
Likely avoid a Corporate Integrity Agreement	Risk of broadening scope of government review/inquiry
Obtain one or more types of releases	Risk of discovery of other, undisclosed overpayments through government inquiry/investigative process; difficult to get FCA release from DOJ
Likely avoid independent government investigation into the matter	No guarantees of leniency, immunity, or specific benefits
Tolls 60 day repayment obligation if funds unavailable for refund	One agency cannot settle for another without express agreement (i.e., cross-referral for further enforcement)
Likely avoid program participation exclusion	Risk of self-disclosure where in fact no overpayment has occurred (differing interpretation or change in law)

Government Enforcement Trends

- Preventative landscape (no longer a "pay and chase" approach to dealing with healthcare fraud)
- SRDPs and SDPs volume generally increase each year
- Several resources dedicated to fraud investigation/prevention
 1. DOJ/HHS's Health Care Fraud and Abuse Control (HC FAC) Program and Health Care Fraud Prevention and Enforcement Action Team (HEAT) (HHS, OIG and DOJ)
 2. False Claims Act (DOJ)
 3. CMS' Fraud Prevention System and other data analytic tools Enhanced Provider Screening and Enrollment
 4. Health Care Fraud Prevention Partnership (public-private insurer effort)
 5. Senior Medicare Patrols: volunteer-led beneficiary education on fraud, waste and abuse

Government Enforcement Trends

Fiscal Year	Federal Healthcare Fraud Judgments and Settlements	# of Investigations	# of Enforcement Actions	# of Criminal Convictions	# of OIG exclusions
2016	\$2.5 billion (\$3.3B returned)	975	480	658	3,635
2015	\$1.9 billion (\$2.4B returned)	983	463	613	4,112
2014	\$2.3 billion (\$3.3B returned)	924	496	734	4,017
2010	\$2.5 billion (\$2.86B returned)	1,116	488	726	3,340
2006	\$2.2 billion (\$1.5B returned)	836	355	547	
2000	\$1.2 billion		467		3,350
1997	\$1.087 billion				2,700 (+98%)

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SRDP Settlement Trends

- Limited public insight
- Taking longer and longer to resolve
- CMS may determine no Stark Law violation via SRDP

Year	# of SRDPs Settled	Settlement \$ Range	Aggregate Settlement \$ Total
2014	41	\$3,322-\$463,473	\$5,175,168
2015	49	\$5,081-\$815,405	\$6,706,458
2016	102	\$80-\$1,195,763	\$6,913,988

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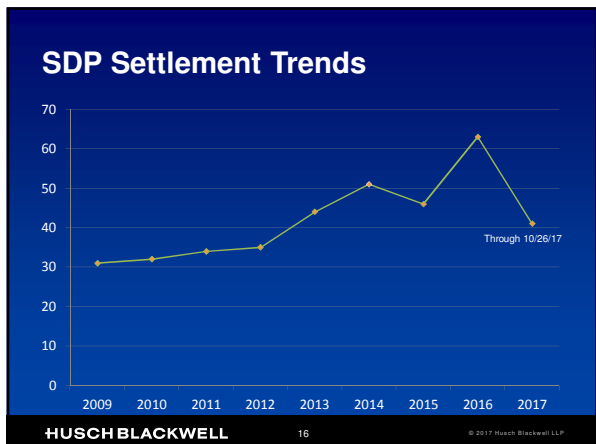
SDP Settlement Trends

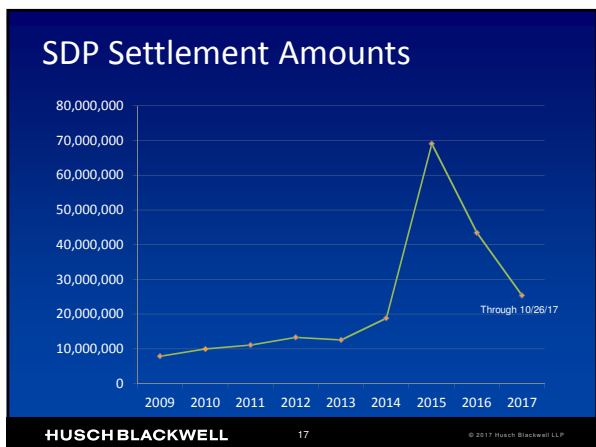
- Revised Protocol requirements to streamline process
- Often OIG requests a "table summary" in post-submission discussions ("cheat sheet")
- Usually resolved within a year; usually accepted within 90 days
- Expect to pay multiplier
- Rarely are CIAs implemented

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The “Do’s” of a Self-Disclosure

- Pre-Disclosure Best Practices:
 - Act on Credible Information of an Overpayment
 - Investigate with Reasonable Diligence
 - Appropriately Quantify the Overpayment
 - Assess and Reassess Your Compliance Program
 - Resolve Problems Causing Overpayments
 - Expect significant investment in process



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The “Do’s” of a Self-Disclosure

- Self-Disclosure Protocol Best Practices:
 - Follow the Protocol Instructions
 - Present everything as a “potential” violation
 - Be complete (and creative), especially in legal analysis
 - Organize Supplemental Documentation
 - Disclosure full period of non-compliant conduct, but financial analysis/overpayment calculation for lookback period only
 - Designated a Sophisticated Contact Person

The “Don’ts” of a Self-Disclosure

- Ignore Credible Information of an Overpayment
- Drag Out the Investigation
- Use an Unreliable or Inaccurate Calculation Methodology to Drive Down the Overpayment Amount
- Overshare
- Talk openly about the Overpayment until Protocol is Filed
- Waive Attorney-Client Privilege without Strategic Consideration of Doing So
- “Wing It”
- Think that Filing the Protocol Is the End of the Road

Post-Disclosure Readiness Tips

- Be Patient
- Cooperate/Respond Timely to Supplemental Requests
- Maintain an annotated version of the Protocol
- Be mindful of attorney-client privilege
- Seek, and Address Bases for, Reduction in Refund Amount
 - Nature and extent of improper/illegal practice
 - Timeliness of Self-Disclosure
 - Cooperation with process
 - Litigation risk
 - Financial position of the provider post-refund
 - Effectiveness of revised compliance plan
- Seek extensive releases (DOJ, OIG, CMS)

Key Takeaways

- Implement a compliance program that effectively identifies overpayments
- Engage counsel to maintain privilege through investigative process
- Prioritize overpayment investigations
- Be strategic in approach to refund
- If utilizing a self-disclosure protocol, be thorough and prepared for questions
- Protocols are designed to encourage compliance, not penalize honesty...but understand the landscape



THANK YOU!
