GEORGIA HEALTH LAW DEVELOPMENTS

A PUBLICATION OF THE HEALTH LAW SECTION OF THE STATE BAR OF GEORGIA

FALL 2013

NOTICE

The articles which are published in *Georgia Health Law Developments* are the sole responsibility of their respective authors, and do not represent any views or opinions of the State Bar of Georgia or of the Health Law Section.

Health Law Section

Health Law Developments

MESSAGE FROM THE CHAIR

Greetings Health Law Section Members,

The Executive Committee has been busy planning this year and we are excited about the Section's activity.

The Health Law Section recently sponsored the informative Fundamentals of Health Law program. Thanks again to program chair Rod Meadows for planning another successful program.

The Section will also be sponsoring the annual Advanced Health Law program November 8th at the Four Seasons in Atlanta. We hope that you will be able to join us. The Executive Committee is currently planning the program and is excited to include a wide range of cutting edge topics.

We would like to thank all of the authors who contributed to this edition of the Health Law Section newsletter. In this most recent edition, Vimala Devassy, Laurice Rutledge and Jennifer Whitton provide an update on the final omnibus HIPAA regulations promulgated as a result of the HITECH Act; Darrell Solomon and Chris Cottrell explore a hospital landlord's options when a physician tenant defaults on lease obligations; Sara Lord informs us about the revised OIG Self-Disclosure Protocol; and, Alan Horowitz educates us on OIG plans to review nursing facilities' administration of atypical antipsychotic drugs. We appreciate Brian McEvoy's assistance editing and publishing the newsletter.

The Executive Committee continually seeks to prepare meaningful programs for our Section and provide you with information relevant to the practice of health care and we hope that you have benefited from these efforts. We invite our members to submit articles, reports, and proposals for presentations that would be informative to the membership.

It is an honor to serve as Chair this year. Please let me or anyone on the Executive Committee know if you have any ideas or suggestions to help us better serve you.

Best regards,

Summer H. Martin
Chair, Health Law Section

CHAIR

SUMMER H. MARTIN
McKenna Long & Aldridge LLP
303 Peachtree Street, NE
Atlanta, GA 30308
Telephone: (404) 527-4910
shmartin@mckennalong.com

IMMEDIATE PAST CHAIR

JAMES W. BOSWELL, III
King & Spalding LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-3534
jboswell@kslaw.com

VICE-CHAIR

BRIAN F. MCEVOY
Chilivis, Cochran, Larkins & Bever, LLP
3127 Maple Drive, NE
Atlanta, GA 30305
Telephone: (404) 233-4171
bfm@cclblaw.com

SECRETARY/TREASURER

MARK KASHDAN
Centers for Disease Control & Prevention
Office of the General Counsel, DHHS
1600 Clifton Road, NE (MS D-53)
Atlanta, GA 30329-4018
Telephone: (404) 639-7448
mtk6@cdc.gov

MEMBERS OF THE EXECUTIVE COMMITTEE

ROBERT D. STONE
Alston & Bird LLP
One Atlantic Center
1201 W. Peachtree St.
Atlanta, GA 30309
Telephone: (404) 881-7270

ERIN C. FUSE BROWN
Assistant Professor of Law
Georgia State University
School of Law
140 Decatur St.
Office 413
Atlanta, Georgia 30303
Telephone: 404-413-9180
efusebrown@gsu.edu

DANIEL J. MOHAN
Morris, Manning & Martin, LLP
1600 Atlanta Financial Center
3343 Peachtree Road, N.E.
Atlanta, GA 30326
Telephone: (404) 504-7616
dmohan@mmmlaw.com

LYNN ADAM
King & Spalding LLP
1180 Peachtree Street
Atlanta, GA 30309
Telephone: (404) 572-3528
ladam@kslaw.com

KEITH MAURIELLO
Arnall Golden Gregory LLP
171 17th Street, NW, Suite 2100
Atlanta, GA 30363-1031
Telephone: (404) 873-8732
keith.mauriello@agg.com

LYNETTE RHODES
Georgia Department of Community Health
2 Peachtree Street, NW, 40th Floor
Atlanta, GA 30303
Telephone: (404) 656-7964
lrhodes3@yahoo.com

BRIAN STIMSON
Alston & Bird LLP
1201 West Peachtree Street
Atlanta, GA 30309-3424
Telephone: (404) 881-4972
bstimson@alston.com

`

PAST CHAIRS

Charlene L. McGinty
Kevin E. Grady
Paul G. Justice
Charity Scott
Eve H. Goldstein
Randall L. Hughes
C. Richard Langley
James R. McGibbon
Jonathan Rue
Jeffrey Baxter
Rod Meadows
William W. Calhoun
Lori Spenser
Kathlynn Butler Polvino
Robert Porter
Tracy M. Field
Charlotte A. Combre
Robert D. Stone
James W. Boswell, III

Welcome, New Executive Committee Member!

**We would like to congratulate and thank
Erin Fuse Brown, Assistant Professor of Law,
Georgia State Law School,
the newest member of the Executive Committee
of the Health Law Section.
Erin immediately involved herself
in the work of the Section,
and we are honored to have her serve.**

Client Alert:
U.S. Department of Health and Human Services Issues HIPAA Omnibus Final Rule

Vimala Devassy, Laurice M. Rutledge and Jennifer Whitton
McKenna Long & Aldridge LLP

On January 17, 2013, the Department of Health and Human Services, Office of Civil Rights (the "Department") published the much anticipated omnibus final regulations to the Health Insurance Portability and Accountability Act of 1996 (the "Final Rule").[1] The Final Rule implements modifications to the following:

1) the HIPAA Privacy and Security Rules to reflect the statutory changes required by the 2009 Health Information and Technology for Economic and Clinical Health ("HITECH") Act;

2) the HIPAA Enforcement Rules;

3) the HITECH Breach Notification for Unsecured Protected Health Information ("Breach Notification Rule"); and

4) HIPAA Privacy Rule to increase privacy protections for genetic information as required by the Genetic Nondiscrimination Act of 2008 ("GINA").

The Final Rule is effective March 26, 2012, and covered entities, which include health care providers and health plans, and their Business Associates have until September 23, 2013 to comply with the modified regulations. We have summarized below the key provisions of the Final Rule.

I. Modifications to the Privacy and Security Rules

The Department made a number of changes to the HIPAA Privacy and Security Rules, including: changes to the definition of business associate and business associates' culpability under these rules; the expansion of individuals' rights to receive electronic copies of their health information and to restrict disclosures to a health plan concerning treatment for which the patient has paid out-of-pocket in full; modifications related to the content of and distribution requirements for covered entities' Notices of Privacy Practices ("NPP"); and changes to the requirements for clinical research authorizations.

A. Business Associates

As set forth in the proposed rule, the Final Rule implements the HITECH Act's requirement that business associates are directly liable for compliance with numerous provisions of the HIPAA Security Rule and the Breach Notification Rules, as well as certain provisions of the HIPAA Privacy Rule. Specifically, under the Security Rule, business associates must implement administrative, physical and technical requirements to safeguard PHI, as well as the Security Rule's policies, procedures and documentation requirements. The Final Rule confirms that business associates are also directly liable for all requirements under the Breach Notification Rule.

Also in accordance with the HITECH Act's requirements, the Final Rule expands the definition of a business associate to include a person or entity that creates, receives, *maintains*, or transmits protected health information ("PHI") to ensure that entities that maintain PHI on behalf of a covered entity (such as physical storage facilities or companies that store PHI in the cloud) are business associates of covered entities, as opposed to mere "conduits." As set forth in the HITECH Rule, the definition of business associate also expressly includes Health Information Organizations, E-Prescribing Gateways, entities that provide data transmission services to a Covered Entity and require access on a routine basis to PHI, entities that offer Personal Health

[1] The Final Rule was published in the January 25, 2013 Federal Register and is available at http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf.

Records ("PHR") on behalf of a covered entity, and subcontractors that have access to or use of PHI.

The Final Rule confirms that business associates are liable for failing to enter into business associate agreements ("BAAs") with their subcontractors, which are defined in the Final Rule as "a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate." Such agreements must contain the same elements as required of BAAs between covered entities and their business associate. Finally, consistent with the HITECH Act, the Final Rule provides that all business BAAs must include the following provisions: (1) business associates are required to comply with the Security Rule with regard to electronic-PHI ("e-PHI"); (2) business associates must report breaches of unsecured PHI to Covered Entities; (3) business associates must ensure that any subcontractors that create or receive PHI on behalf of a business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information; and (4) to the extent that a business associate is to carry out a covered entity's Privacy Rule obligations, the business associate must comply with the requirements of the Privacy Rule that apply to the covered entity in performance of such obligation. Since many companies revised their business associate agreements to comply with the HITECH Act in 2009, these changes in the Final Rule may not require wholesale revision of business associate agreements if they were already implemented at that time.

Covered entities and business associates are required to comply with these new BAA requirements by September 23, 2013. However, due to concerns expressed by numerous commenters regarding the time frame for compliance with this requirement, the Department added a transition provision that allows covered entities and business associates to continue to operate under their existing agreements until September 23, 2014. This extension period is available to covered entities and business associates that implemented their existing HIPAA-compliant BAAs prior to the publication date of the Final Rules, as long as these entities do not renew or modify their agreements after March 26, 2013. However, any new BBAs entered into after January 25, 2013 must comply with the Final Rule by September 23, 2013.

B. Marketing

The Final Rule significantly revised the definition of marketing to provide that any communications for which the covered entity receives financial remuneration, which is defined as direct or indirect payment in exchange for making the communication, is considered marketing, and a covered entity must first obtain authorization by the patient to make such a communication. Prior to the Final Rule, patient authorization was not required to make communications related to treatment and health care operations so covered entities could use PHI to send marketing communications, such as recommending alternative therapies, without obtaining authorization from the patient or beneficiary. However, the Final Rule now provides that such treatment or health care operation communications will be considered marketing communications requiring patient authorization if the covered entity, or its business associate, receives any remuneration in exchange for making the communication.

C. Disclosures to Health Plans

The Final Rule amends the Privacy Rule's provisions regarding an individual's right to require restrictions for certain uses and disclosures of PHI. Under the Final Rule, a covered entity is required to agree to a request by an individual to restrict the disclosure of PHI to a health plan if the PHI pertains solely to a health care item or service for which the individual (or a person on behalf of an individual) has fully paid the covered entity out of pocket. The Final Rule clarifies that health care providers are not required to create separate medical records or segregate PHI for which a patient has paid in full out of pocket; however, health care providers must implement some system to flag or notate any PHI that has been restricted in an individual's medical record. Since covered entities' billing and medical record systems may not currently have the ability to implement such requests for restrictions, this requirement could be costly and burdensome for covered entities to implement.

D. Research Authorizations

The Final Rule streamlines the process for compound authorizations (*i.e.*, authorizations for the use and disclosure of PHI which are combined

with any other legal permissions) and future research authorizations. HIPAA previously prohibited compound authorizations where (1) the authorization conditioned treatment, payment, enrollment in a health plan, or eligibility for benefits (the "conditioned authorization") with (2) an authorization for another purpose for which treatment, payment, enrollment, or eligibility may be not be conditioned ("unconditioned authorization"). The Final Rule now allows a covered entity to combine conditioned and unconditioned authorizations, provided that the authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual to opt in to the unconditioned research activities.

Additionally, while the Privacy Rule previously required that research authorizations be study specific, which precluded the use of PHI for use or disclosure in future research studies, the Final Rule clarifies that authorizations for the use and disclosure of PHI for future research are permitted. However, these authorizations for future research must include a description of the potential purposes for which the PHI may be used and disclosed in the future.

E. Modified Period of Protection for Decedent PHI

Previously, the Privacy Rule required that covered entities protect the privacy of a decedent's PHI in the same manner and to the same extent that is required for PHI of living individuals. Thus, if an authorization is required for a particular use or disclosure of PHI, a covered entity must obtain an authorization from the decedent's personal representative, which was often difficult, particularly after the estate is closed. Consequently, the Final Rule modified this requirement and a covered entity is now required to comply with the Privacy Rule, with regard to the PHI of a deceased individual, for a period of 50 years following the date of death.

F. Notice of Privacy Practices

Covered entities are required to develop and distribute a Notice of Privacy Practices ("NPP") pursuant to the existing HIPAA Privacy Rule. Under the Final Rule, covered entities must modify their NPP to contain a statement indicating that most uses and disclosures of psychotherapy notes, uses and disclosures of PHI for marketing purposes, and disclosures that constitute a sale of PHI require authorization. The NPP must also generally state that other uses and disclosures not specifically described in the notice will be made only with the individual's authorization. If a covered entity intends to contact an individual for fundraising purposes, the Final Rule now requires that the NPP notify individuals of their right to opt out of such communications. Additionally, the Final Rule requires that an NPP inform individuals of their new right to restrict certain disclosures to PHI to health plans where the individual pays out of pocket in full, as well as a statement of the right of affected individuals to be notified following a breach of unsecured PHI.

A health plan must prominently post a revised NPP on its website by September 23, 2013 or provide information on its website about the Final Rule's material changes to the notice and how to obtain the health plan's revised NPP. Health care providers must revise their form of NPP and post the revised NPP on their website, or post the revised NPP in a prominent place in their service delivery site and make the revised NPP available to patients after September 23, 2013.

II. Modifications to the Enforcement Rule

The Final Rule also significantly modified the Enforcement Rule. Prior to the Final Rule, the Enforcement Rule provided an exception for: a covered entity's liability for the acts of its agents in cases where (1) the agent is a business associate; (2) the relevant business associate contract requirements were met; (3) the covered entity did not know of a pattern or practice of the business associate in violation of the contract; and (4) the covered entity did not fail to act as required by the Privacy or Security Rule with respect to such violations. The Final Rule significantly amends the Enforcement Rules and removes this exception for covered entities in its entirety, and adds a new parallel provision that provides for civil money penalty liability against business associates for the act of their agents. As a result, covered entities are now directly liable for any Security Rule breaches made by their agents, and business associates are now responsible for any breaches made by their subcontractors and agents. Thus, covered entities and business associates should consider reviewing the indemnification provisions of BAAs in the event that the covered entity or business associate is found liable for the acts of an agent.

The Final Rule also adopted the civil money penalty tiers previously established by the Interim Final Rule, which provided for increasing civil money penalty amounts for violations based on the levels of culpability associated with each tier. Under this system, a covered entity or business associate has the potential to incur as much as $50,000 for each violation, with a cap of $1,500,00.

III. Modifications to the Breach Notification Rule

The Final Rule now *presumes* that an impermissible use or disclosure of PHI is a breach requiring a notification, unless the covered entity or business associate demonstrates that there is a low probability that the PHI has been compromised. Previously, the Breach Notification Rule allowed covered entities to utilize a "risk of harm" analysis to determine whether a breach occurred, which required an evaluation of whether there was a significant risk of harm to the individual as a result of the impermissible use or disclosure. However, the risk of harm threshold has been removed in the Final Rule. In its place, a multifactor risk assessment must be conducted if an impermissible use or disclosure occurs.

The Department has defined the following factors that a covered entity or business associate must consider in their risk assessment:

- The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
- The unauthorized person who used the PHI or to whom the disclosure was made;
- Whether the protected health information was actually acquired or viewed; and
- The extent to which the risk to the PHI has been mitigated.

Breach notification is not required if the risk assessment demonstrates there is a low probability that the PHI has been compromised. Accordingly, covered entities and business associates will need to revise their policies to remove the risk of harm threshold as the basis for determining if a breach has occurred and replace this standard with the modified risk assessment outlined above.

IV. Modifications of HIPAA Privacy Rule As Required by GINA

GINA prohibits discrimination based on an individual's genetic information in both the health coverage and employment contexts. The Final Rule amends the HIPAA Privacy Rule to clarify that PHI includes genetic information and that a health plans (other than issuers of long term care policies) may not use or disclose genetic information for underwriting purposes.

A Hospital's Obligation In the Event of Default by a Physician Tenant

Darrell Solomon and Chris Cottrell
McKenna Long & Aldridge LLP

With the Affordable Care Act's increased focus on curtailing fraud and abuse in federal healthcare programs, it has become increasingly important for hospitals and other healthcare providers to ensure regulatory compliance with applicable healthcare laws. In particular, hospitals should be concerned with maintaining appropriate financial relationships with physicians and physician group practices. This article focuses on the relationship formed when a physician rents space owned by a hospital and, more specifically, examines a hospital's responsibilities in the event the physician defaults on his or her lease agreement.

In the modern healthcare delivery system, physicians and physician group practices often lease medical office facilities from hospitals. And while the Stark law and anti-kickback statute generally prevent the leasing physician from referring patients to the landlord hospital, the referral relationship is permitted to exist as long the lease meets certain requirements (it is in writing, signed by both parties, has at least a one year term, is commercially reasonable, etc.)[1]

However, while the obligations in forming a compliant lease are specific and relatively clear, the obligations placed upon a hospital when its tenant physician defaults on that lease are much less clear. Indeed, a hospital's failure to collect rent on physician lease agreements can lead to severe consequences in the form of monetary penalties. In 2009 for example, Tulare Local Healthcare District in California faced allegations that it had, among other things, failed to collect – and subsequently forgave debts – on physician lease agreements. Tulare was forced to pay over $2.4 million in order to settle with DOJ. Similarly, Rush Medical Center in Illinois was forced to enter a settlement with DOJ for over $1.5 million as a result of comparable allegations.

Considering the monetary penalties associated with violations of Stark and anti-kickback laws, it is imperative that hospitals not only execute leases which conform to the requirements of those laws, but also enforce their rights under such leases. However, when faced with an insolvent physician, or a physician who refuses for some other reason to pay on a lease agreement, it may at some point become economically unreasonable for the hospital to continue to pursue that debt. Unfortunately, there is little commentary that provides insight into what a hospital is obligated to do in such situations, and at what point the hospital can write off the debt without violating federal healthcare laws. As such, an examination of what hospitals are required to do in the pursuit of debt in other contexts may be instructive.

In the context of physician debt owed to a hospital as a result of a breached physician recruitment agreement, one commentator has suggested that hospitals are required at a minimum to treat the debt as it would any other debt owed to the hospital.[2] For example, if a hospital's policies dictate that it must refer debt to a collection agency after a certain number of days, that hospital should take at least those steps in pursuing the physician debt. This rationale holds true in the context of physician debt incurred under a lease agreement. Further, hospitals should document and preserve all of their collection efforts in preparation for the potentiality of future scrutiny under Stark and anti-kickback laws.

The guidelines setting out the requirements a provider must meet before it can declare uncollected deductibles and coinsurance amounts from Medicare beneficiaries as "bad debt" are also instructive, as they provide clear guidance on what a federal healthcare program deems to be sufficient efforts undertaken before declaring a debt uncollectible.[3] Among other things, a provider desiring to claim debts owed by Medicare beneficiaries as uncollectible must show that it made reasonable collection efforts and that sound business judgment established that there was no likelihood of recovery of the debt in the future. CMS has explained that to be considered a reasonable collection effort, the provider's effort to collect from Medicare beneficiaries must be similar to its efforts to collect from non-Medicare beneficiaries.[4] Indeed, the Medicare Manuals

provide that "[i]t must involve the issuance of a bill . . . [and] include other actions such as subsequent billings, collections letters and telephone calls or personal contacts with the [debtor]. The provider's collection effort may include using or threatening to use court action to obtain payment."[5]

In pursuing debts owed by physicians on lease agreements, initiating the sorts of efforts described above may be a good starting point for hospitals before they decide to write off the debt. While these guidelines are not authoritative in determining a hospital's compliance with the Stark law and the anti-kickback statute, these sorts of efforts will likely go a long way in showing that writing off physician debt was not made in an attempt to induce referrals. Rather, the effort was made in congruence with sound business judgment.

It is unsettled precisely what the Stark and anti-kickback laws require of a hospital faced with a physician unable or unwilling to pay on a lease agreement. It may indeed be necessary, in order to avoid potentially ongoing violations of the Stark and anti-kickback laws, to initiate dispossessory proceedings once it becomes clear that rent will not be forthcoming. Hospital personnel faced with such a situation should keep in mind that the driving principal behind the lease exception to Stark and anti-kickback is commercial reasonableness. Put simply, a hospital's actions must make economic sense without taking into account the value or volume of referrals received from the physician. Accordingly, the hospital must at minimum ensure that it undertakes the efforts it would normally pursue to obtain payment on any other debt.

---

[1] *See* 42 U.S.C. § 1395nn(e)(1)(a); 42 C.F.R. § 1001.952(b).

[2] http://www.healthlawyers.org/SiteCollectionDocuments/MemberForum%20Oct09_FINAL.pdf.

[3] 42 CFR § 413.89(e).

[4] Using this rationale, a hospital's efforts to collect physician debt incurred under a lease agreement should be similar to its collection efforts against individuals or entities from which it does not receive patient referrals.

[5] Medicare Provider Reimbursement Manual, Part I, Chapter 3 § 310.

MESSAGE FROM THE EDITOR
CALL FOR AUTHORS

The Health Law Section of the State Bar of Georgia is pleased to provide a publication for its members to address current topics of interest. We encourage you to send us summaries of recent cases, legislation, and agency activities that may be of interest to health law attorneys who practice in Georgia and the Southeast. Suitable short feature articles on timely topics may also be accepted for publication. Please address inquiries, submissions, and suggestions to:

BRIAN F. MCEVOY
Chilivis, Cochran, Larkins & Bever, LLP
3127 Maple Drive, NE
Atlanta, GA 30305
Telephone: (404) 233-4171
bfm@cclblaw.com

OIG Plans to Review Nursing Facilities' Administration of Atypical Antipsychotic Drugs

Alan Horowitz
Arnall Golden Gregory LLP

Former Director of Nursing Sentenced to 3 Years in Prison for "Convenience Drugging"

On January 9, 2013, California Attorney General Kamala D. Harris issued a Press Release describing why a former Director of Nursing (DON) at a skilled nursing facility was sentenced to three years in state prison. The DON entered a plea of "no contest" to a felony count of elder abuse with an added allegation that the abuse contributed to the death of a nursing home resident. One of the criminal counts against the former DON was "assault with a deadly weapon, to wit, Risperdal, a psychotropic medicine." The facility's former medical director and a former pharmacist were also charged with elder abuse, resulting in death; elder abuse with infliction of injury; and assault with a deadly weapon (the psychotropic medications).

The former DON "ordered" psychotropic medications for 22 residents "not for therapeutic reasons, but instead to control and quiet them for the convenience of staff," according to the Attorney General's (AG) Office. When at least one of those residents refused the medications, he was "held down and injected with the psychotropic medicine by force." Additionally, three residents died as a result of the "convenience drugging," while the others suffered serious adverse effects, such as weight loss, lethargy and dehydration, according to official documents.

According to a sworn declaration filed by a Special Agent for the California Department of Justice, who conducted an investigation, the former DON would initiate Interdisciplinary Team (IDT) meetings to discuss the behavior of some of the facility's residents. During these meetings, she directed the pharmacist to write prescriptions for psychotropic medications for some of the residents. The pharmacist then wrote the orders and the nurses administered the medication to the residents.

On multiple occasions, residents were forcibly injected with the psychotropic medications, according to the Special Agent. The medical director signed the orders after the IDT meetings - sometimes, three weeks after the medication was given. Additionally, he failed to examine the residents to determine if the psychotropic medications were medically necessary, according to the AG.

The facility's former CEO was alleged to have allowed the forcible "convenience drugging" to continue after she knew about its existence. She was charged with conspiracy to commit an act injurious to the public health based on her failure to adequately supervise the DON, whom she had hired. After pleading "no contest," the former CEO was sentenced to three years formal probation and 300 hours of volunteer service. The former medical director was also sentenced to 300 hours of volunteer service and was placed on probation by the California Medical Board. As a condition of probation, he is prohibited from practicing medicine in skilled nursing facilities, convalescent homes and assisted living facilities during his probation.

Why Is the Use of Psychotropics Important to Health Care Providers?

The type of case described above is highly unusual and fortunately rare. However, health care facilities, and especially skilled nursing facilities can expect heightened scrutiny regarding their levels and patterns of psychotropic medication use. Each year, the U.S. Department of Health and Human Services, Office of the Inspector General (OIG) issues its Work Plan. According to the Fiscal Year 2013 OIG Work Plan, OIG will be reviewing nursing facilities' administration of atypical antipsychotic drugs, both in terms of the percentage of residents receiving these drugs as well as the types of drugs being administered.

In May 2011, OIG released a report, *Medicare Atypical Antipsychotic Drugs Claims for Elderly Nursing Home Residents*, in which it noted that in 22% of the atypical antipsychotic

claims it reviewed, the medications "were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes."[1] A little more than a year later, in July 2012, OIG released another report dealing with antipsychotic drugs, *Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs*.[2] In that report, OIG determined that 99 percent of the records it reviewed failed to comply with one or more federal requirements.

The extent of inappropriate psychotropic drug use is underscored by a recent letter from the American Medical Directors Association (AMDA) to nursing facility medical directors. In its June 18, 2012 correspondence, AMDA asked the medical directors of facilities "to join with AMDA and [the Centers for Medicare & Medicaid Services], in the nationwide effort to reduce the unnecessary use of antipsychotic agents by refocusing the interdisciplinary team on a better understanding of the root cause of dementia related behaviors."[3]

CMS previously expressed the goal of reducing antipsychotic medications by 15% by the end of 2012. Nursing facilities should expect that State agency surveyors, CMS and OIG will be closely scrutinizing their use of antipsychotic medications in 2013. Towards that end, and in keeping with providing quality care, facilities should ensure that their initial resident comprehensive assessment, subsequent assessments and care planning are properly performed and implemented. Whenever clinically feasible, psychotropic drug doses should be gradually decreased and eliminated, if appropriate. Adequate documentation, including all related diagnoses, should support the drug and dose. (It is a violation of federal regulations to administer "unnecessary drugs" or drugs used as "chemical restraints.")

Providers should consider availing themselves of the many tools and educational programs available for free that assist facilities in reducing and eliminating the use of psychotropic medications. For example, AMDA as well as organizations such as the American Health Care Association and initiatives such as Advancing Excellence in America's Nursing Homes, offer useful techniques, sample policies and clinical practice guidelines aimed at reducing antipsychotic medication usage.

---

1 Department of Health and Human Services, Office of the Inspector General, *Medicare Atypical Antipsychotic Drugs Claims for Elderly Nursing Home Residents*, OEI-07-08-00150 (May 2011).

2 Department of Health and Human Services, Office of the Inspector General, *Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs*, OEI-07-08-00151 (July 2012).

3 American Medical Directors Association, *"Dear Medical Director"* (June 18, 2012), available at: http://www.amda.com/advocacy/antipsychotic_msg.pdf. Last accessed on January 23, 2013.

OIG Revises Self-Disclosure Protocol (SDP)

Sara Lord
Arnall Golden Gregory LLP

On April 17, 2013, the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) published the revised Provider Self-Disclosure Protocol (SDP), which replaces and supersedes the original SDP issued in 1998, as well as the three Open Letters providing additional guidance in 2006, 2008, and 2009.[1] The SDP establishes a process for health care providers to voluntarily identify, disclose, and resolve instances of potential fraud involving federal health care programs, including guidance on how to investigate the conduct, quantify damages, and report the conduct. The revised SDP, which comes after the OIG's June 18, 2012 solicitation for public comments, clarifies the eligibility requirements for participation in the process, sharpens the requirements for the disclosure submission, outlines methods of calculating damages, and expedites the time frame for the disclosing party to complete its internal investigation and damages calculation.

Among the "significant benefits" to an organization that self-discloses fraudulent conduct to the OIG, the revised SDP lists: (1) an institutional presumption against requiring integrity agreement obligations in exchange for a permissive exclusion release; (2) a lower multiplier (typically, 1.5 times) on single damages than would normally be required in resolving a government-initiated investigation; and (3) based on anticipated rule changes to be made by the Centers for Medicare & Medicaid Services (CMS), suspension of the obligation under Section 1128J of the Social Security Act to report overpayments so long as the SDP submission is timely made, and suspension of the obligation to return overpayments until the disclosure matter has been resolved.[2]

Including a streamlined process and timely resolution of SDP events among the benefits of the program, the revised SDP shortens the time period for disclosing parties to complete their internal investigations and damages calculations. Under the new SDP, disclosing parties must submit their investigative findings and estimated damages within 90 days of making their initial submission under the SDP, instead of within 90 days of acceptance into the SDP.

Eligibility for the SDP

The revised SDP clarifies that the SDP is not limited to any particular industry, medical specialty, or type of service. All individuals or entities subject to the OIG's Civil Monetary Penalties (CMP) authority, including pharmaceutical or medical device manufacturers, are eligible to use the SDP. If a disclosing party is already the subject of a government investigation, the party may still use the SDP, as long as the disclosure is made in good faith and is not an attempt to circumvent any ongoing inquiry. Parties under Corporate Integrity Agreements (CIA) may also use the SDP in addition to making any reports required in the CIA.

The SDP may be used to resolve liability for potential violations of federal criminal, civil, or administrative laws for which CMPs are authorized. The revised SDP specifies, however, that a disclosing party must acknowledge that the conduct is a potential violation, and explicitly identify the laws that were potentially violated. Conduct that is not eligible for the SDP includes: (1) matters exclusively involving overpayments or errors; (2) requests for OIG opinions as to whether actual or potential violations may have occurred; and (3) arrangements that involve only liability under the physician self-referral law (the Stark Law) and do not also include liability under the Anti-Kickback Statute (AKS).[3]

[1] http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf

[2] Additional guidance on this point will be provided on the OIG website after CMS issues its final rule.

[3] If the arrangement raises a potential violation of only the AKS or of both the AKS and the Stark Law, the arrangement should be disclosed to OIG under the SDP. If the arrangement raises a potential violation of only the Stark Law, the arrangement should be disclosed to CMS under the SRDP.

As a condition for acceptance into the SDP, the disclosing party must agree to waive any statute of limitations defenses to any administrative actions related to the disclosed conduct (unless that defense would have been available on the date of submission). The disclosing party is also required to ensure that the conduct has ended and/or that corrective action will be taken.

The SDP Submission

In order to be considered for admission to the SDP, the disclosing party must now include the following information in its submission:

- Identifying information, including an organizational description of the disclosing party;
- A "concise statement of all details relevant to the conduct disclosed;"
- A statement of the federal criminal, civil, or administrative laws potentially violated by the disclosed conduct;
- The federal health care program affected by the disclosed conduct;
- An estimate of the damages, or a certification that the estimate will be completed and submitted within 90 days of the date of submission;
- A description of the disclosing party's corrective action upon discovery of the conduct;
- A statement of whether the disclosing party has knowledge that the matter is under current inquiry by a government agency or contractor;
- The name of an individual authorized to enter into a settlement agreement; and
- A certification.

Disclosures of Conduct Involving False Billing

When a disclosure involves false or fraudulent billings, the disclosing party must conduct a review to estimate the improper amount paid by the federal health care programs, and prepare a report of its findings. The estimation of damages must consist of a review of either: (1) all the claims affected by the disclosed matter or (2) a statistically valid random sample of the claims that can be projected to the population of affected claims. Where a sample is used, the disclosing party must use a sample of at least 100 items and the mean point estimate to calculate damages. The revised SDP also clarifies that, in calculating the damages estimate, the disclosing party may not include an offset for any underpayments discovered during the review.

The report of the damages estimate must include:

- A statement clearly articulating the objective of the review;
- A description of the group of claims, an explanation of the methodology used to develop the population, and the basis for this determination;
- A full description of the source of the data;
- The names, titles, and qualifications of the individuals who conducted the review; and
- The characteristics used for testing each item.

If the estimation of damages was based upon a sample, the review report must also include a description of the sampling plan that was followed, and the sampling plan must meet the minimum requirements listed in the revised SDP.

Disclosures of Conduct Involving Excluded Persons

In addition to providing the detailed information required in the original submission, disclosures involving excluded persons must include:

- Identifying information of the excluded individual;
- The job performed by the excluded individual;
- The dates of the individual's employment;
- A description of the background checks that were completed before and/or during the individual's employment;
- A description of the screening process and any flaws or breakdowns that led to the hiring of the excluded individual;
- A description of how the conduct was discovered; and
- A description of any corrective action to prevent future hiring of excluded individuals.

Before making the disclosure, however, the disclosing party must also screen all current employees and contractors against the OIG's List of Excluded Individuals and Entities. The revised SDP also provides guidance for calculating damages in cases involving excluded individuals.

Disclosures of Conduct Involving the Anti-Kickback Statute and Physician Self-Referral Law

For disclosures under the AKS and the Stark Law, the revised SDP reiterates the requirement that the disclosing party must acknowledge that the subject arrangement(s) constitute potential violations of the AKS and, if applicable, the Stark Law. ("OIG will not accept any disclosing party into the SDP that fails to acknowledge clearly that the disclosed arrangement constitutes a potential violation of the AKS and, if applicable, the Stark Law.") The disclosing party must include in its narrative submission "a concise statement of all details directly relevant to the disclosed conduct and a specific analysis of why each disclosed arrangement potentially violate the AKS and Stark Laws." The revised SDP also requires more information on the parties' relationships to one another, the payment arrangements, and the dates of the arrangements – as well as an explanation of the context and features of the arrangements that raise potential liability under the statutes.

While the determination of the settlement amount depends on the individual facts and circumstances of each matter, for matters involving AKS and potential Stark Law liability, the OIG typically uses an amount based upon a multiplier of the remuneration provided under the suspect arrangement. The damages estimate, therefore, must include the total amount of remuneration involved in each arrangement without regard to whether the disclosing party believes that some of the remuneration involved a lawful purpose. The revised SDP emphasizes, however, that, although the OIG generally uses the remuneration-based methodology as an incentive to encourage disclosure of potential AKS violations, this does not govern its position in other situations where another measure may be used.

Settlement

OIG will coordinate with the Department of Justice (DOJ) civilly and criminally in resolving SDP matters, and advocate, in both instances, that the disclosing party receives a benefit from disclosure under the SDP.

Although OIG does not require an admission of liability in settlement agreements, the revised SDP warns that disclosing parties should expect to pay above single damages, and states that OIG's "general practice" is to require a minimum multiplier of 1.5 times the single damages. While the multiplier is applied to the amount paid by the federal health care program, not to the amount claimed, OIG does require minimum settlement amounts for self-disclosed matters. For kickback-related matters, OIG will now require a minimum $50,000 settlement; for all other matters accepted into the SDP, OIG will require a minimum $10,000 settlement amount.

Conclusion

While the revised SDP offers more explicit guidance to disclosing parties, the changes – notably in the required content and acknowledgements in the submission – place greater burdens on disclosing parties. Similarly, to the extent that the revised SDP clarifies the benefits of self-disclosure, it makes clear that those benefits must be earned by the disclosing party. Individuals and entities planning to self-report actual or potential violations may expect a faster and more consistent process, but will have to do a great deal more work themselves.

State Bar of Georgia
104 Marietta St. NW, Suite 100
Atlanta, GA 30303

Presorted
Standard Mail
US Postage Paid
Atlanta, GA
Permit No. 1447