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CMS Issues Transparency Reporting Proposed Rule

The Centers for Medicare and Medicaid Services' proposed rule, which will implement Section 6002 of the Patient Protection and Affordable Care Act, clarifies several definitions, provides further information on reporting requirements, and offers guidance on submitting required information.

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On December 14, the Centers for Medicare and Medicaid Services (CMS) published its long-awaited proposed rule, "Transparency Reports and Reporting of Physician Ownership or Investment Interests." The proposed rule will implement Section 6002 of the Patient Protection and Affordable Care Act (ACA), popularly known as the U.S. Sunshine Act. It largely mirrors the ACA statutory provisions but also provides significant clarification and potential expansion of the scope of the provisions. The proposed rule was published in the December 19 edition of the *Federal Register*. View a copy of the proposed rule at http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf.

IMMEDIATE IMPLICATIONS

The sky is not falling, but it is necessary for all companies and institutions to promptly assess the practical implementation costs and enhancements needed for current accounting, procurement, accounts payable, and compliance policies and procedures. While waiting for the proposed rule, many life science companies have already begun implementing such transparency efforts voluntarily, both to get a jump-start on the required implementation and to otherwise comply with state marketing statutes. A few large pharma companies are subject to Department of Health and Human Services (HHS) Office of Inspector General (OIG) Corporate Integrity Agreements (CIAs) that have transparency provisions and have already successfully implemented those provisions. CMS estimates the average cost for implementation will be approximately $170,000 annually for most companies, which may be a low estimate. The transparency provisions should be considered in context, taking into consideration all stakeholders, including healthcare professionals and institutions, and how compliance with the provisions will require changes to contracts and arrangements. These stakeholders, which include physicians, hospitals, academic medical centers, and nursing homes, have their own, additional transparency compliance requirements in ACA, and many entities are implementing their own policies to deal with transparency reporting.

CMS is now soliciting substantial comments from the public on the proposed definitions, exclusions, and processes related to applicable manufacturer reporting of payments or transfers of value provided to physicians or teaching hospitals (covered recipients), as well as applicable manufacturer and applicable

group purchasing organization (GPO) reporting of certain physician ownership or investment interests. To ensure consideration, **CMS must receive comments no later than 5 p.m. ET on February 17, 2012.**

Notably, the proposed rule delayed the January 1, 2012 start of applicable manufacturer and GPO information collection until CMS issues its final rule. The March 31, 2013 reporting deadline set by statute has not changed.

THE PROPOSED RULE

The purpose of the proposed rule is to provide for transparency in the relationship between covered recipients and applicable manufacturers. Once final, the rule would require any applicable manufacturer that provides a payment or other transfer of value (TOV) to a covered recipient to report information annually to HHS regarding any such payments or TOV for the preceding calendar year, with some exceptions. Generally, only those payments or TOV $10 in value or greater would need to be reported, unless the aggregate amount to a covered recipient during a calendar year exceeds $100. The rule would also require an applicable manufacturer or applicable GPOs to report any ownership or investment interest held by a physician in the applicable manufacturer or applicable group purchasing organization, with some exceptions.

Morgan Lewis has prepared a coordinated chart summarizing the statute, its proposed implementing regulations, and the nearly 60 questions for which CMS is soliciting comments from the public. (View the Morgan Lewis chart summary at http://www.morganlewis.com/documents/HealthIndustryTransparencyRequirements.pdf.) Changes of note are discussed below.

Key Definitions Drive Application of Provisions

The proposed rule clarifies the definitions of several of the terms in ACA, affecting who is excluded from its reporting requirements. There is also guidance on submitting required information to HHS. For information on specific definitions, please see the "Definitions" section in the chart linked above.

Definitions of "Covered Drug, Device, Biological, and Medical Supply"

Notably, CMS is proposing to limit drugs and biologicals in the definition of "covered drug, device, biological, and medical supply" to drugs and biologicals that, by law, require a prescription to be dispensed, thus excluding drugs and biologicals that are considered "over the counter" (OTC).

CMS is additionally limiting the definition of "covered drug, device, biological, and medical supply" as it pertains to devices and medical supplies, which would limit them to those devices (including medical supplies) that, by law, require premarket approval by or notification to the Food and Drug Administration (FDA). This definitional limitation would exclude many Class I devices and certain Class II devices.

The definitions of "covered drug, device, biological, and medical supply" are limited to those devices that require premarket approval. Furthermore, the proposed rule's expanded definitions of these terms considerably affect Medicare reimbursement. This is of significance to Health IT and other companies

that do not sell traditionally or directly reimbursed products to the hospital community and may not fall within the definition of a product for which reimbursement is available.

ACA defines "covered drug, device, biological, or medical supply" as "any drug, biological product, device, or medical supply *for which payment is available* under title XVIII [Medicare] or a State plan under title XIX [Medicaid] or XXI [SCHIP] (or a waiver of such a plan)." CMS expands this definition in the proposed rule by defining the same terms as "any drug, device, biological, or medical supply for which payment is available under Title XVIII [Medicare] or under a State plan under Title XIX [Medicaid] or XXI [SCHIP] (or a waiver of such plan), *either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration*" (emphasis added).

What is unclear from the proposed rule is how devices purchased by hospitals that are not directly included in the provision of service to a patient and not factored into calculation of a composite payment will be treated for purposes of Medicare reimbursement. For example, when a hospital purchases health IT equipment, the purchase is likely treated as a capital expenditure. An extraordinarily small portion of the composite payment is designed to reimburse hospitals for their overhead and capital expenditures.

Who Is a Physician Under the Statute?

The statute is designed to capture industry-compensated relationships and transfers of value with physicians. As part of its definition of what constitute a "covered recipient," the proposed rule defines the term "physician" by reference to section 1861(r) of the Social Security Act. The Social Security Act's definition of "physician" is based on a doctor of medicine's or osteopathy's legal authorization to practice medicine by the state in which he or she performs such function.

Covered Teaching Hospitals Defined by GME Payments

Moreover, the same "covered recipient" definition states that only "*teaching* hospitals" (e.g., any institution that received a payment under section 1886(d)(5)(B) (IME) or 1886(h) (GME), or 1886(s) (psychiatric hospitals IME) of the Social Security Act) fall within the definition (emphasis added). Interpreting this definition strictly, payments or other transfers of value to the nation's numerous community hospitals would not need to be reported because they are not *teaching* hospitals, and thus not covered by the proposed rule.

GPOs Are Covered Recipients

CMS noted that the definition of applicable GPO will not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians). CMS's stated intention is to capture entities *(including physician-owned entities)* that purchase covered drugs, devices, biologicals, or medical supplies for resale or distribution to others.

Charity Care Defined

CMS specifically defined "charity care" as items provided to a covered recipient for one or more patients who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay. Charity care does not include the provision of in-kind items to a covered recipient, even if the covered recipient is a charitable organization, for the care of all of the covered recipient's patients (both those who can and cannot pay).

Exclusions

Express Exclusions from Definitions of TOV

The proposed rule tracks ACA's numerous exclusions for TOV for which applicable manufacturers are not required to submit information. These include the following:

- TOV made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in Section 403.902) the identity of the covered recipient.
- A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 during the calendar year. For calendar years after 2012, the dollar amounts shall be increased by the same percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.
- Product samples that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
- The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.
- Discounts (including rebates).
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of healthcare to employees under the plan.
- In the case of a covered recipient who is a licensed nonmedical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the nonmedical professional services of the licensed nonmedical professional.
- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

CMS suggested that generally applicable manufacturers should use dictionary definitions in interpreting these exclusions. This may prove confusing and inconsistent. For example, discounts and rebates are excluded from reporting, but discounts have different definitions under the federal Anti-Kickback Statute and various best price drug reporting requirements. *Webster's II New College Dictionary* defines "discount" as, among other things, "A reduction from the full or standard amount of a price or debt." This dictionary definition may help define the discount exclusion but may not advance a uniform regulatory interpretation for compliance purposes.

Other Key Exclusions: Actual Patient Education Materials and Buffet Meals at Medical Conferences

The proposed rule provides additional guidance for several of the exclusions. For example, CMS stated that educational materials must consist of actual *materials* (such as pamphlets) that directly benefit patients or that are intended for patient use. This term includes both written and electronic materials, but it does not include services or other items. Furthermore, CMS is considering whether certain materials provided by applicable manufacturers to covered recipients to educate the covered recipients, but which are not actually given to patients (e.g., medical textbooks), should be interpreted as educational materials that "directly benefit patients."

Significantly, CMS proposed that applicable manufacturers do not need to report any offerings of buffet meals, snacks, or coffee at booths at conferences or other similar events where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings.

Indirect Third-Party Payments Exclusion Clarified

Indirect third-party payments have been forecast as a large loophole of the transparency provisions, and the proposed rule attempts to clarify the exclusion by explaining that for indirect payments through a third party turns on whether an applicable manufacturer is "unaware" of the identity of the covered recipient. In order to protect against abuse of this exclusion, CMS proposes in the rule that an applicable manufacturer is aware of the identity of a covered recipient if the applicable manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient.

Product Development Arrangements with HCPs and Institutions

A sleeper issue of great significance is the reporting of payments to healthcare providers (HCPs) that involve proprietary research and product development before commercialization. The statute contains protection provisions for these situations and the proposed regulations address delayed publication of payments made to HCPs and institutions pursuant to product research or development agreements and clinical investigations. According to the proposed rule, such payments must be reported to CMS on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following: (1) the date of the approval, licensure, or clearance of the covered drug, device, biological, or medical supply by the FDA; or (2) four calendar years after the date such payment or other transfer of value was made.

The Reporting Process

CMS detailed the processes for submitting required information. Under the proposed rule, any applicable manufacturer or applicable GPO that is required to report must register with CMS before March 31, 2013. For applicable manufacturers under common ownership who want to file a consolidated report, such report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers.

If an applicable manufacturer or applicable GPO discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon discovery of the error or omission.

Finally, each report, including any subsequent corrections thereto, must include a certification by the chief executive officer, chief financial officer, or chief compliance officer of the applicable manufacturer or applicable GPO that the information submitted is true, correct, and complete to the best of his or her knowledge and belief.

Before such information is made public, however, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for at least 45 days. CMS will notify the above entities when the reported information is ready for review. As proposed, the above entities may log into a secure website where each applicable manufacturer, applicable GPO, covered recipient, and physician owner is able to view the information reported specific to it.

Despite some pronounced departures from ACA, the proposed rule largely tracks the statutory language. The proposed rule clarifies several definitions, provides further information on reporting requirements, and offers much-needed guidance on submitting required information. Many questions and concerns still remain. CMS has specified close to 60 areas in which they would like the public to comment, many of which focus on the administrative and financial burden of collecting and reporting the required information.

Preemption of State Law Provisions—Not So Much

The proposed rule's preemption provision follows the express preemption provision in ACA. Section 6002 of the ACA contains a preemption provision that impacts previously enacted physician payment reporting requirements for drug and device manufacturers in the District of Columbia, Maine, Massachusetts, Minnesota, Vermont, and West Virginia. The federal preemption is not absolute, however, as it applies only to the extent the state laws require reporting of the same information. The preemption does not apply to (1) state laws or regulations that require reporting of different information; (2) reporting by entities other than manufacturers, physicians, or hospitals; or (3) reporting to a federal or state agency "for public health surveillance, investigation, or other public health purposes or health oversight purposes." Healthcare entities subject to Section 6002 requirements still need to anticipate managing transparency requirements at the federal and state levels.

RESOURCES TO ASSIST IN YOUR TRANSPARENCY COMPLIANCE

Morgan Lewis will hold a brown bag audio session on Thursday, January 5, 2012 to provide an overview of the proposed rule and to line up discussion on a few of the rule's major requirements. We

will also host a webinar on Thursday, January 26, 2012 to discuss into the nuances of the proposed rule and to discuss areas in which CMS has requested public comment. We encourage you sign up for these upcoming events on CMS's implementing regulations and what they mean for the life sciences and healthcare industries. Register for our January 5 audio session at http://www.morganlewis.com/events/transparencycompliancecall. Register for the January 26 webinar at https://morganlewisevents1.webex.com/.

Additionally, Morgan Lewis will review questions submitted to its Transparency Compliance Resource Center at TransparencyCompliance@MorganLewis.com. Morgan Lewis is currently organizing comments to the proposed regulations from a variety of interested and coordinated perspectives.

Morgan Lewis represents device and drug companies in government-mandated transparency disclosure requirements as well as counsels healthcare corporations and institutions on compliance with various state reporting requirements. We will continue to monitor the development of government transparency requirements.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact **Kathleen McDermott** (202.739.5458; kmcdermott@morganlewis.com) or any of the following members of our Transparency Compliance team: **Michele Buenafe** (202.739.6326; mbuenafe@morganlewis.com), **Jonathan Havens** (202.739.5952; jhavens@morganlewis.com); or **Rebecca Osowski** (202.739.5009; rosowski@morganlewis.com).

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