CMS FINAL RULE ON REPORTING OF PAYMENTS OR TRANSFERS OF VALUE AND PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS

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February 12, 2013

MEMORANDUM

FROM: Alan M. Kirschenbaum
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SUBJECT: CMS Final Rule on Reporting of Payments or Transfers of Value and Physician Ownership or Investment Interests

On February 8, 2013, over 16 months beyond its statutory deadline, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register a long-awaited final rule on the reporting of certain payments or transfers of value and physician ownership or investment interests by applicable manufacturers and applicable group purchasing organizations (GPOs) under section 6002 of the Patient Protection and Affordable Care Act (PPACA). The rule contains a number of significant changes from CMS’ proposed regulation published in December 2011.

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2 For convenience, this memorandum refers to “payments or transfers of value” simply as “payments.”
PPACA section 6002 added to the Social Security Act (SSA) new section 1128G, which requires the submission of two reports. First, section 1128G(a)(1) requires applicable manufacturers of drugs, devices, biologicals, or medical supplies that are covered under Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP) to report annually to the Secretary of Health and Human Services (HHS) certain payments or other transfers of value to covered recipients. Second, section 1128G(a)(2) requires applicable manufacturers and applicable GPOs to report information on ownership or investment interests in such entities held by physicians or their immediate family members, and also to report information on payments and other transfers of value to physicians holding such ownership or investment interests.

This memorandum summarizes the key provisions of the final rule, pointing out significant changes from the proposed regulation.

I. REPORTS ON PAYMENTS AND OTHER TRANSFERS OF VALUE (TRANSPARENCY REPORTS)

A. Who Must Submit Reports?

Transparency reports must be submitted by “applicable manufacturers.” CMS has defined “applicable manufacturer” as an entity that is “operating in the United States” and that falls within one of the following categories:

(1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such [product] is solely for use by or within the entity itself or by the entity’s own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

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5 Codified at 42 U.S.C. § 1320a-7h.
(2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.\(^6\)

The above definition contains several significant changes from the proposed definition, and CMS has also included a number of clarifications in the preamble. These are outlined below.

1. Foreign manufacturers

The statute provides that a manufacturer must be operating in the U.S. or one of its territories, possessions, or commonwealths in order to be considered an “applicable manufacturer.”\(^7\) In the proposed regulation, CMS had essentially read that limitation out of the law, taking the position that a manufacturer operates in the U.S. if the manufacturer’s products are sold or distributed here, regardless of where the entity is located or incorporated.\(^8\) The final rule gives effect to the statutory limitation, albeit in a limited fashion. The rule defines “operating in the United States” to mean that an entity has a physical location in the U.S. or its territories or possessions, or otherwise conducts activities there, either directly or through a legally-authorized agent.\(^9\) The preamble states that CMS considers “conducting activities” to include selling a product.\(^10\) Presumably, therefore, a company that is located outside the U.S. but maintains a sales

\(^6\) 42 C.F.R. § 403.902 (2013). All references to section numbers are to 42 C.F.R., except where otherwise indicated.

\(^7\) 42 U.S.C. § 1320a-7h(e)(2).

\(^8\) See 76 Fed. Reg. at 78,744.

\(^9\) § 403.902.

\(^10\) 78 Fed. Reg. at 9461.
force (or contracts to have one) in the U.S. falls within the definition. On the other hand, a company that merely contributes to the manufacture of a product, but has no business presence in the U.S., does not fall within the definition.\textsuperscript{11}

2. Hospitals and Compounding Pharmacies

CMS has added language excluding from the definition of “applicable manufacturer” an entity that prepares a product for use within the entity or by the entity’s own patients.\textsuperscript{12} The preamble explains that this revision excludes entities such as hospitals, hospital-based pharmacies, and laboratories that prepare a covered product solely for use by the entity’s own patients. The preamble also states that the exclusion applies to compounding pharmacies if they (1) comply with state laws regulating the practice of pharmacy, (2) regularly engage in dispensing prescription drugs or devices, and (3) do not prepare drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail to individual patients.\textsuperscript{13} (These three conditions appear in the preamble but not the regulation itself.)

3. Wholesalers, Distributors, and Repackagers

CMS has also revised prong (1) of the “applicable manufacturer” definition (i.e., an entity engaged in the “production, preparation, propagation, compounding, or conversion” of a covered product) to add the following exclusionary sentence: “This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug.

\textsuperscript{11} Id.
\textsuperscript{12} § 403.902.
\textsuperscript{13} 78 Fed. Reg. at 9461.
device, biological or medical supply.” This exclusion will be helpful to repackagers, relabelers, and kit assemblers who perform these services under contract but never obtain title to (i.e., purchase) the products. However, because most wholesalers and distributors purchase and obtain title to the products they subsequently distribute, the exclusion will not apply to these entities. Nevertheless, under the regulation, a wholesaler or distributor who takes title still must be engaged in the “production, preparation, propagation, compounding or conversion” of a covered product in order to be a prong (1) applicable manufacturer,” or must be rendering “assistance or support” to an affiliated prong (1) manufacturer in order to be a prong (2) applicable manufacturer.

In the preamble, CMS articulates a puzzling interpretation that “distributors and wholesalers (which include repackagers, relabelers, and kit assemblers) that hold title to a covered drug, device, biological or medical supply meet the definition of an applicable manufacturer for the purpose of this rule” because, like manufacturers, they hold title to covered products at some point in the production and distribution cycle. For wholesalers and distributors who do not repack, relabel, or assemble, but merely purchase and distribute covered products unchanged, this statement necessarily means that CMS believes mere distribution to constitute “production, preparation, propagation, compounding, or conversion.” If this is CMS’ view, it is contrary to the language of the statute. Mere distribution does not fall within the plain meaning of either “production,” “preparation,” “propagation,” “compounding,” or “conversion.” Moreover, this list of activities is substantially similar to those included since 1962 in the Federal Food, Drug, and Cosmetic Act’s definition of manufacturers subject to drug and device registration

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14 § 403.902.
and listing.\textsuperscript{16} The FDC Act and implementing FDA regulations do not require registration and listing of firms who merely distribute and do not repackage or otherwise change the container, wrapper, or label of the product.\textsuperscript{17}

Even if the plain meaning of the terms listed in prong (1) were not a definitive indicator of Congress’ intent, the presence of the term “distribution” in prong (2) of the applicable manufacturer definition (relating to affiliates), together with its absence in prong (1), is conclusive evidence that the omission in prong (1) was deliberate and Congress did not intend prong (1) to encompass mere distribution. Moreover, prior versions of this definition in predecessor bills included “distribution” in addition to production, preparation, propagation, compounding, and conversion, but the term was removed in prong (1) of the definition in the bills that eventually became PPACA, further demonstrating that Congress deliberately intended prong (1) not to apply to mere distribution. In light of the congressional intent, CMS’ preamble statement is highly questionable.

4. Manufacturing by Contract; Contract Manufacturers

CMS has not changed its position that “applicable manufacturers” include entities that hold FDA approval, licensure, or clearance of a covered product, and who contract out the physical manufacturing of the product to another entity.\textsuperscript{18}

\textsuperscript{16} 21 U.S.C. § 360(a). In the FDC Act definition, the term “processing” appears in place of “conversion.”

\textsuperscript{17} Id. § 360(a)(1); 21 C.F.R. § 207.3(a)(8).

\textsuperscript{18} 78 Fed. Reg. at 9462.
With respect to reporting by contract manufacturers themselves, CMS has added a provision that a manufacturer who only manufacturers a covered product under a written manufacturing agreement, does not hold FDA approval, licensure, or clearance for the covered product, and is not involved in its sale, marketing, or distribution, is only required to report its payments or other transfers of value that are made in reference to or in connection with a covered product.\textsuperscript{19} The preamble clarifies, however, that a manufacturer who contract manufactures some products, but also manufactures at least one covered product that is not under a contract manufacturing agreement, must report all of its payments in compliance with the regulation.\textsuperscript{20} This additional provision will make little difference in practice, since most firms that manufacture exclusively under contract, not being involved in the sale, marketing, or distribution of products they manufacture, would have no payments or transfers of value to report even absent the new provision.

5. One Covered Product Sufficient, but Ten Percent Threshold Applies

Rejecting objections from commenters, CMS has not changed its position that a manufacturer that sells or distributes at least one covered product in the U.S. is considered an applicable manufacturer, even if the entity sells other products that are not covered products, and that an applicable manufacturer must report all payments, even if they are not associated with the covered product.\textsuperscript{21} However, in a concession to companies whose primary business focus is not the production of covered products but who may still produce one or a few such products, CMS has added a provision that an applicable manufacturer whose gross revenues from covered products constituted less

\textsuperscript{19} § 403.904(b)(4).
\textsuperscript{20} 78 Fed. Reg. at 9462.
\textsuperscript{21} Id.
than ten percent of total gross revenue during the fiscal year preceding the reporting year is only required to report payments or other transfers of value that are related to (i.e., “made in reference to or in connection with”) a covered product.\(^\text{22}\) This will relieve such companies from having to report a multitude of payments that are related to non-covered products (i.e., over-the-counter (OTC) drugs or 510(k)-exempt devices) or unrelated to any specific products.

6. **Affiliates and Operating Divisions**

The final rule contains several clarifications regarding prong (2) of the definition of “applicable manufacturer” – i.e., an entity under common ownership with a prong (1) manufacturer, which provides “assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution” of a covered product.\(^\text{23}\) CMS declined to alter its proposal that “common ownership” exists where the same individual or entity directly or indirectly owns five percent or more total ownership of two entities.\(^\text{24}\) However, CMS did add clarifications that significantly narrow the scope of the prong (2) definition. First, prong (2) applicable manufacturers are only required to report payments or other transfers of value that are related to a covered product for which they provided assistance or support to the affiliate who is a prong (1) manufacturer.\(^\text{25}\) Second, applicable manufacturers (under either prong) with operating divisions that do not manufacture covered products need only report payments made by those divisions if they are related to

\(^{22}\) § 403.904(b)(1); see also 78 Fed. Reg. at 9462-9463.

\(^{23}\) § 403.902.

\(^{24}\) § 403.902.

\(^{25}\) § 403.904(b)(2).
Finally, CMS has added a new definition of “assistance and support,” defining the term as providing a service that is “necessary or integral” to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. Thus, for example, a company that merely assists a prong (1) affiliate with human resources services is not an applicable manufacturer under prong (2).

B. What is a Covered Drug, Device, Biological, or Medical Supply?

CMS has retained the substance of its proposal to define a covered drug, device, biological, or medical supply as any drug, device, biological, or medical supply for which “payment is available” under Medicare, Medicaid, or CHIP, either separately or as part of a bundled payment (for example, the hospital inpatient or outpatient prospective payment system). In addition, covered drugs or biologicals include only those that, by law, require a prescription to be dispensed, so that OTC drugs are not covered. Devices or medical supplies are covered only if, by law, they require premarket approval by the FDA or premarket notification (i.e., 510(k) clearance), so that Class I devices and 510(k)-exempt Class II devices are not covered.

The preamble clarifies that a product that is not approved or cleared may nevertheless be a covered product if “payment is available” for it under Medicare or Medicaid. For example, payment is available under Medicare for certain devices covered

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26 § 403.904(b)(3); see also 78 Fed. Reg. at 9464.

27 § 403.902.


29 § 403.902.
under an investigational device exemption (IDE), and payment may be available under Medicaid for certain unapproved pre-1962 prescription drugs.\textsuperscript{30}

The preamble explains that, when a manufacturer’s first product becomes eligible for payment under Medicare, Medicaid, or CHIP, CMS will allow a grace period of 180 days after the product becomes “covered” before the manufacturer must begin complying with the data collection and reporting requirements.\textsuperscript{31}

C. Who are Covered Recipients?

Section 1128G(e)(6) defines “covered recipient” as (1) a physician as defined under section 1861(r) of the SSA (for purposes of Medicare), other than a physician employed by an applicable manufacturer, or (2) a teaching hospital.\textsuperscript{32} Physicians include doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors. However, residents in these disciplines are not covered recipients.\textsuperscript{33}

Teaching hospitals are not defined in the statute, but CMS defines them as any institution that received payments for direct or indirect graduate medical education (GME) under Medicare during the most recent year.\textsuperscript{34} CMS will publish a list of all such hospitals on its web site annually, at least 90 days before the beginning of the reporting year, and manufacturers can rely on the list for the entire reporting year.\textsuperscript{35}

\textsuperscript{30} 78 Fed. Reg. at 9465.
\textsuperscript{31} Id. at 9463.
\textsuperscript{32} 42 U.S.C. § 1320a-7h(e)(6); see also § 403.902.
\textsuperscript{33} 78 Fed. Reg. at 9467.
\textsuperscript{34} § 403.902.
\textsuperscript{35} 78 Fed. Reg. at 9470.
D. What Payments or Other Transfers of Value Must Be Reported?

The regulation requires applicable manufacturers to report “direct and indirect payments or other transfers of value” to (1) a covered recipient, or (2) “a third party at the request of or designation by the applicable manufacturer on behalf of a covered recipient ….”\(^{36}\) Tracking the statute, the regulation defines a “payment or other transfer of value” as “a transfer of anything of value.”\(^{37}\) The rule sets forth a number of exclusions, which are described in Section I(G), below. In addition, the preamble provides general guidance on determining reported value. First, CMS considers “value” to mean the discernable economic value on the open market in the U.S. All aspects of the value, such as taxes or shipping, should be included in the reported value. Beyond this, CMS declines to provide rules for calculating value. Manufacturers must make a reasonable, good faith effort to determine the value of a payment or transfer of value, and may include the methodology used in a voluntary assumptions document that is submitted to CMS.\(^{38}\)

The preamble clarifies that a payment made “at the request of” a covered recipient means that the covered recipient has directed the applicable manufacturer to provide the payment to another entity or individual rather than receiving it personally. A payment that is “designated on behalf of a covered recipient” is one where the covered recipient does not receive the payment, but the applicable manufacturer provides the payment to another entity in the name of the covered recipient – for example, a fee waived by a physician and then donated by an applicable manufacturer to a charity on behalf of the

\(^{36}\) § 403.904(a).

\(^{37}\) § 403.902.

\(^{38}\) 78 Fed. Reg. at 9470-9471.
Physician. Both types of payments are to be reported under the name of the covered recipient, but also including the name of the entity that received or payment, or, if an individual received it, the designation “individual” (so as to preserve the privacy of such individuals).

E. **What Are the Contents of the Report?**

Applicable manufacturers must report to CMS the following information regarding any payment or transfer of value to a covered recipient.

1. **Name.** For physicians, the name must be reported as listed in the National Plan and Provider Enumeration System (NPPES) on CMS’s web site, for those physicians listed therein. The first and last name and middle initial must be included, as applicable.

2. **Primary business address.**

3. **Physician specialty, license number, and National Provider Identifier (NPI).** As in the proposal, CMS is requiring reporting of a physician’s specialty and NPI. NPIs may be found on the NPPES database on CMS’s website. The preamble explains that manufacturers should be able to demonstrate that they made a good faith effort to obtain an NPI for a physician, which includes checking the NPPES database, calling the NPPES help desk, and requesting the NPI from the physician. If good faith efforts fail, the NPI field may be left blank. Not reporting an NPI for a physician who has one will

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39 Id. at 9472.
40 § 403.904(c)(10).
41 § 403.904(c).
be considered inaccurate reporting.\textsuperscript{42} In addition, CMS has added a requirement to provide the physician’s state license number.

(4) \textit{Amount of Each Payment.} The value of payments to a group practice should be attributed to the individual physicians who requested or are intended to benefit from the payment, but not necessarily to all members of the practice. For example, a dermatology textbook provided to a group practice should be attributed only to the dermatologists in the practice by dividing the cost equally among them.\textsuperscript{43}

(5) \textit{Date of Payment.} This is the date upon which a payment was provided to the covered recipient. For payments spanning multiple dates, applicable manufacturers may, in their discretion, report the total payment on the first payment date as a single line item or report each individual payment as a separate line item.

(6) \textit{Related Covered Drug, Device, Biological, or Medical Supply.} If the payment is “related to” (defined as “made in reference to or in connection with”) a covered drug or biological, the marketed name of the product and the National Drug Code (NDC) must be disclosed, or, if a name has not yet be selected, the name registered on clinicaltrials.gov. For devices and medical supplies, either the marketed name, therapeutic area, or product category must be provided. If the payment is related to a specific non-covered product, “non-covered” should be indicated (but not the name of the non-covered product), and if the payment is not related to any product (covered or not), “none” should be indicated.\textsuperscript{44} Manufacturers may report up to five related covered products for each payment or transfer.\textsuperscript{45}

\textsuperscript{42} 78 Fed. Reg. at 9468-9469.

\textsuperscript{43} \textit{Id.} at 9471.

\textsuperscript{44} \textit{Id.} at 9474.

\textsuperscript{45} \textit{Id.} at 9475.
(7) **Payment to physician with ownership interest.** The applicable manufacturer must indicate whether the payment was made to a physician or immediate family member who holds an ownership interest or investment interest in the manufacturer (as discussed in Section II, below).

(8) **Delayed publication.** The applicable manufacturer must indicate whether the payment is a research payment subject to delayed publication (see Section I(F)(2), below).

(9) **Form of Payment.** The form of the payment or other transfer of value must be indicated using one of the following categories:

1. Cash or cash equivalent
2. In-kind items or services
3. Stock, a stock option, or any other ownership interest
4. Dividend, profit, or other return on investment

(10) **Nature of Payment.** The nature of each payment must be indicated using only one of the following categories.

1. Consulting fees
2. Compensation for services other than consulting, including serving as faculty or a speaker at other than a continuing education program (discussed below)
3. Honoraria
4. Gift
5. Entertainment
6. Food and beverage (discussed below)
7. Travel and lodging (including the specified destinations)
8. Education
9. Research (discussed below)
10. Charitable contribution (discussed below)
11. Royalty or license
12. Current or prospective ownership or investment interest
13. Compensation for serving as faculty or as a speaker for an unaccredited medical education program (discussed below)
14. Compensation for serving as faculty or as a speaker for an accredited medical education program (discussed below)
15. Grant
16. Space rental or facility fees (teaching hospital only)

The rule and preamble elaborate further on “natures” reporting in general and on certain of the above categories:

Payments with multiple categories: Only one nature may be indicated for each payment. If a payment could fit within several categories, the manufacturer should select the most suitable one, but should not bundle payments belonging to separate categories into a single payment. For example, a meal should be reported as a meal, even if it is associated with travel or a consulting contract.\(^{46}\)

Charitable contributions: This category should only be used where an applicable manufacturer makes a payment to a charity on behalf of a covered recipient, but not in exchange for any service or benefit. For example, if a physician requests that his or her consulting fee be paid to a charity, this should be reported, not as a charitable contribution, but as a consulting fee with the physician as the covered recipient and the charity as the entity paid.\(^{47}\)

\(^{46}\) Id. at 9476.

\(^{47}\) Id. at 9478.
Meals and Beverages: In response to strong objections from commenters, CMS has revised its proposed policy on the reporting of meals provided to physicians in a group setting, which would have required attributing the value of such meals to all physicians in a group, even if the physician did not partake of the meal. Under the final rule, the cost of meals provided in a group setting is instead to be divided by the total number of individuals who ate the meal (both physicians and non-physicians, such as office staff), with the resulting per-person cost reported for each physician who actually ate the meal.\textsuperscript{48} Additionally, CMS is excluding reporting of buffet meals, snacks, soft drinks, or coffee made generally available to all participants at large-scale conferences or similar events.\textsuperscript{49}

Payments for CME and speaker fees: In a welcome departure from the proposed rule, CMS has revised the treatment of payments for faculty at CME events. Payments for CME that is accredited by the ACCME or other specified accrediting organizations are exempt from reporting if the applicable manufacturer does not pay faculty directly and does not select or recommend individual faculty members. If a CME program is accredited, but the manufacturer directly pays or recommends the faculty, the payments must be reported as “Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.” If a program is not accredited, the payment is reported as “Compensation for serving as a faculty or as a speaker for an unaccredited and non-certified continuing education program.”\textsuperscript{50} Finally, where a payment is made to a physician speaker at an event that is not continuing medical education (for example, a promotional speaker program), the payment should be reported as

\textsuperscript{48} § 403.904(h); see also 78 Fed. Reg. at 9478-9479.

\textsuperscript{49} Id.

\textsuperscript{50} § 403.904(g); see also 78 Fed. Reg. at 9479-9480.
“Compensation for services other than consulting, including serving as faculty or a speaker at other than a continuing education program.”

“Other” Category Deleted: The final rule omits the proposed “other” nature category because it would dilute the usefulness of the nature categories. CMS cautions that all payments to covered recipients must be reported, and failure to identify a “nature” category could result in penalties. Therefore, manufacturers should select the nature category that most closely describes the payment.

F. Research Payments

1. Reporting Research Payments

Under the final rule, payments for research are reported separately from other payments and transfers of value, using a different reporting format. Responding to objections from commenters that the proposed rules on reporting of research payments were confusing and duplicative, CMS has simplified its approach to such reporting. To begin with, “research” is defined with reference to the definition in the Public Health Services Act, which includes basic and applied research, preclinical research, Phase I through IV studies, and investigator-initiated studies. If a payment falls within the definition of research and is subject to a written agreement, a protocol, or both, it is reported as research. Research-

51 § 403.904(e)(2)(ii); see also 78 Fed. Reg. at 9480.
52 78 Fed. Reg. at 9480.
53 42 C.F.R. § 50.603 (“Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health … [including] basic and applied research … and product development ….”).
related payments that do not meet these requirements must be reported using other “nature” categories.

In a departure from the proposed regulation, manufacturers will not be required to indicate whether a research payment is direct or indirect, and will not be required to attribute the entire research payment made to a facility to each principal investigator. Instead, the manufacturer will report each research payment once, identifying the name and address of the institution (whether or not a teaching hospital) or individual physician paid, the amount, the name of the study, the name of the related product, and information about each principal investigator. Manufacturers may optionally report explanatory information about the study. The requirements for reporting payments for pre-clinical studies are similar, but no associated product or study name need be reported.\(^{54}\)

2. Delayed Publication of Research Payments

Section 1128G(c)(1)(E) of the SSA requires CMS to delay publication of payments or other transfers of value from applicable manufacturers to covered recipients made (1) pursuant to a product research or development agreement or (2) in connection with a clinical investigation regarding a covered product.\(^{55}\) In the final rule, CMS continues its constrained reading of the statute, making a distinction between the two. Under the final rule, as under the proposed rule, delayed publication will apply to payments for both research and development, and clinical investigations, where they relate to a new product. However, where a new application of an existing product is concerned, publication will be delayed for a research and development payment but not

\(^{54}\) § 403.904(f); see also 78 Fed. Reg. at 9483-9484.

\(^{55}\) 42 U.S.C. § 1320a-7h(c)(1)(E).
for a clinical investigation payment.\textsuperscript{56} In other words, payments to clinical investigators will be entitled to delayed publication if the investigation is for a new product, but not if it is for a new indication of a currently marketed product.

CMS defines “research” as “a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.”\textsuperscript{57} In the preamble, CMS states that “payments related to research on new applications of existing products will be granted a delay only if the research does not meet the definition of ‘clinical investigation,’”\textsuperscript{58} which is “any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, biological or medical supply is administered, dispensed or used.”\textsuperscript{59} CMS goes on to say that it believes “clinical investigation” is broad enough to include Phases I through IV clinical research for drugs and biologicals, and approval trials for devices (including medical supplies).\textsuperscript{60} Given this interpretation, the only payments for “research” of new indications of marketed products that would be subject to delayed disclosure would be payments for non-clinical studies.

\textsuperscript{56} § 403.910(a).
\textsuperscript{57} § 403.902.
\textsuperscript{58} 78 Fed. Reg. at 9505.
\textsuperscript{59} § 403.902.
\textsuperscript{60} 78 Fed. Reg. at 9505.
CMS clarifies in the preamble that a product for which approval will be sought under an ANDA or a 510(k) notification are considered new products, rather than new applications of existing products.\textsuperscript{61}

The final regulation requires that, while the payments or other transfers of value eligible for delayed publication must be reported to CMS in the year after which the payment occurs, CMS will not publicly post the payment until the first annual publication date after the earlier of: (1) the date of the approval, licensure or clearance by FDA of the covered drug, device, biological, or medical supply; or (2) four calendar years after the date of payment.\textsuperscript{62}

Despite comments that CMS should not publish the payments until after FDA approval, licensure, or clearance, CMS stated in the preamble that it believes “Congress clearly intended that all payments should be included on the public website, even if a product never received FDA approval, licensure or clearance.”\textsuperscript{63}

For publication to be delayed, the applicable manufacturer must indicate in its transparency report whether a payment or other transfer of value is eligible for a delay in publication. The failure to indicate eligibility will result in the payment being posted publicly in the following year. The applicable manufacturer must also continue to indicate annually that FDA approval, license, or clearance is pending, and must subsequently notify CMS if FDA approves or clears the product.\textsuperscript{64}

\begin{footnotes}
\item[61] Id.
\item[62] § 403.910(c).
\item[63] 78 Fed. Reg. at 9505.
\item[64] § 403.910(d).
\end{footnotes}
G. Exclusions

Under the statute and the final regulation, the following payments and other transfers of value are excluded from the reporting requirements.\(^{65}\)

(1) Transfer through third party. No reporting is required for a transfer of value made indirectly to a covered recipient through a third party in cases where the applicable manufacturer does not know the identity of the covered recipient. Borrowing the definition of “knowledge” from the Federal False Claims Act, the regulation provides that an applicable manufacturer is considered to have “knowledge” of the covered recipient’s identity if the manufacturer has actual knowledge of, acts in deliberate ignorance of, or acts in reckless disregard of, the identity of the covered recipient.\(^ {66}\)

In response to comments, CMS made several changes that clarify and/or limit the potential scope of the third party rule. First, in order that manufacturers not incur a reporting obligation where a third-party recipient passes an un-earmarked payment through to a physician contrary to the intent or expectation of the manufacturer, CMS has defined “indirect payments or transfers of value” as those that an applicable manufacturer “requires, instructs, directs, or otherwise causes the third party to provide” to a covered recipient.\(^ {67}\) For example, if a manufacturer gave an unrestricted donation to a professional association to use at the organization’s discretion, and the association chose to use the donation to make grants to physicians, the donation would not be a reportable indirect payment, even if the manufacturer learned the identity of the recipient physicians, because the manufacturer did not direct the association to use the donation for

\(^{65}\) § 403.904(i).

\(^{66}\) § 403.902.

\(^{67}\) § 403.902; see also 78 Fed. Reg. at 9489-9491.
that purpose. On the other hand, if the manufacturer directed that the donation be used to make grants to physicians, the donation would be a reportable indirect payment, even though the manufacturer did not earmark the donation to specific physicians. 68

Second, the preamble clarifies that manufacturers will not be considered to be in “deliberate ignorance or reckless disregard” of a covered recipient’s identity where the purpose for making the payment through a third-party is to preserve the anonymity of the recipient. For example, a manufacturer’s payment to a market research firm to provide to physician respondents in a blinded market research study would not be reportable. 69

Third, CMS has retained the policy that the awareness of an applicable manufacturer’s agent of the identity of a recipient is attributed to the manufacturer itself. However, the preamble clarifies that an agent is not merely any third party, but must be a legal agent acting on behalf of the manufacturer.

Finally, to place a time limit on the period in which a manufacturer will be responsible for tracking a recipient’s identity, the regulation provides that a manufacturer is deemed to be unaware of such identity if the manufacturer does not know the identity during the reporting year or by the end of the second quarter of the subsequent reporting year. For example, if a manufacturer provides a contribution in November 2013 to a professional society expressly to be used for grants to physicians, and the association awards the grants in May 2014 and informs the manufacturer of the names of the recipients in June 2014, the payments will be reportable by the manufacturer (in 2014).

69 Id. at 9490.
However, if the association does not inform the manufacturer of the names of the recipients until July 2014, the contribution will not be reportable.\textsuperscript{70}

(2) \textit{De minimis payments}. Payments and transfers of value less than $10 are not reportable, unless the aggregate amount transferred to, requested by, or designated on behalf of a covered recipient exceeds $100 in a calendar year. Small items that are under $10 (such as pens and notepads) that are provided at large-scale conferences and similar large-scale events are exempted from the reporting requirements, and also do not need to be tracked for purposes of the $100 aggregate threshold.

(3) \textit{Samples}. Product samples not intended to be sold and intended for patient use, including coupons and vouchers, are not reportable.

(4) \textit{Educational materials}. Educational materials that directly benefit patients or are intended to be used by or with patients are not reportable. CMS has clarified that this exemption does not cover materials provided to physicians for their own education, nor does it cover marketing or promotional materials.\textsuperscript{71} This narrow interpretation imposes a considerable burden on manufacturers, who must report the value of all reprints and promotional materials provided to physicians if they exceed the \textit{de minimis} threshold. On the other hand, CMS explains that the exemption does cover anatomical models and other items that are intended to be used with a patient.\textsuperscript{72}

(5) \textit{Devices for evaluation}. Manufacturers need not report the loan of a covered device for a short-term trial period, not to exceed 90 days, or the provision of a limited quantity (i.e., 90 days of average use) of disposable or single use devices or medical

\textsuperscript{70} Id. at 9491.

\textsuperscript{71} Id. at 9486.

\textsuperscript{72} Id.
supplies, to permit evaluation of the covered device by the covered recipient. The exemption for disposable or single use devices or supplies was added in the final rule.

(6) Warranty items. Items or services provided under a contractual warranty (including a service or maintenance agreement), including the replacement of a covered device, are not reportable where the terms of the warranty are set forth in the purchase or lease agreement for the covered device. The exemption applies even if the warranty period has expired.

(7) Charity care. Manufacturers are not required to report in-kind items used for the provision of charity care, defined as care for a patient who is unable to pay or for whom payment would be a significant hardship, where the covered recipient does not receive or expect to receive payment. This exemption does not include in-kind items provided to a charitable organization for the care of all of its patients, both those who can and cannot pay. Moreover, the exemption covers only in-kind items, not financial support for charity care.\(^73\)

(8) Covered recipient who is a patient. Reporting is not required for a payment or transfer of value to a physician who is a patient, research subject, or participant in data collection for research, and not acting in the professional capacity of a physician.

(9) Discounts and rebates are not reportable.

(10) Publicly traded securities. A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund is not reportable.

\(^{73}\) Id. at 9486-9487.
(11) *Health care for employee.* In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan are not reportable.

(12) *Payments for non-medical services.* Where a physician is also a licensed non-medical professional, a payment to the physician is non-reportable if it is solely for the non-medical professional services of the individual.

(13) *Payments for services in judicial proceeding.* Manufacturers need not report payments to a physician if the payment is solely for the services of the physician with respect to a civil or criminal action or an administrative proceeding.

(14) *Personal relationship.* A payment to a physician is not reportable if it is made solely in the context of a personal, non-business-related relationship.

II. **REPORTS ON PHYSICIAN OWNERSHIP AND INVESTMENT INTERESTS**

In addition to transparency reports, section 1128G(a)(2) of the SSA requires applicable manufacturers and applicable GPOs to report information on ownership or investment interests in such entities held by physicians or their immediate family members.\(^\text{74}\)

\(^{74}\) 42 U.S.C. § 1320a-7h(a)(2).
A. Definitions

1. Applicable Manufacturer

Section 1128G(a)(2) of the SSA defines applicable manufacturers in the same manner as Section 1128G(a)(1).\(^{75}\)

2. Applicable Group Purchasing Organization

CMS finalized its proposed definition of “applicable GPO” as:

[A]n entity that: (1) [o]perates in the United States; and (2) [p]urchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.\(^{76}\)

CMS states in the preamble that this definition includes purchasers and physician owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies,\(^{77}\) but does not include bulk purchasers for commonly owned entities.\(^{78}\)

3. Physician and Immediate Family Member

“Physician” is defined in the same manner as in Section 1128G(a)(1), except that there is no exception for a physician who is an employee of the applicable manufacturer or GPO. CMS finalized the definition of “immediate family member” as:

\(^{75}\) § 403.902.

\(^{76}\) Id.

\(^{77}\) 78 Fed. Reg. at 9493.

\(^{78}\) Id.
1. Spouse
2. Natural or adoptive parent, child, or sibling
3. Stepparent, stepchild, stepbrother, or stepsister
4. Father-, mother-, daughter-, son-, brother-, or sister-in-law
5. Grandparent or grandchild
6. Spouse of a grandparent or grandchild.\(^79\)

The final rule does not require applicable manufacturers and applicable GPOs to report the name and relationship of immediate family members of the physicians holding the ownership or investment interests in the manufacturers or GPOs.\(^80\) It does allow reporting of aggregate interests across multiple immediate family members. The family members must have interests with the same terms, and the value reported must be the total value of the interests of all family members.\(^81\)

4. Ownership or Investment Interests

CMS finalized the definition of an ownership or investment interest in an applicable manufacturer or applicable GPO in a manner similar to the definition in the physician self-referral regulation (42 C.F.R. § 411.354(b)), which is an interest that may be direct or indirect, and through debt, equity, or other means.\(^82\) This interest may include stock, stock options, partnership shares, loans, and bonds. However, an ownership or investment interest does not include any publicly traded security or mutual fund, nor any of the following:

\(^79\) § 403.902.
\(^80\) 78 Fed. Reg. at 9494.
\(^81\) Id.
\(^82\) § 403.902.
(i) An interest in an applicable manufacturer or applicable GPO that arises from a retirement plan offered by that applicable manufacturer or applicable GPO to the physician (or a member of his or her immediate family) through the physician’s (or immediate family member’s) employment with that applicable manufacturer or applicable GPO;

(ii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity;

(iii) An unsecured loan subordinated to a credit facility.\(^{83}\)

Applicable manufacturers and GPOs need not report indirect ownership or investment interests held by physicians or their immediate family members about which the applicable manufacturers or GPOs did not know.\(^{84}\) This is consistent with the physician self-referral rule.

B. **Physician Ownership and Investment Report Content**

Applicable manufacturers and applicable GPOs must report the following information for each physician ownership or investment interest.\(^{85}\)

1. Applicable manufacturer’s or GPO’s name
2. Physician owner or investor’s
   a. Name
   b. Specialty

\(^{83}\) Id.

\(^{84}\) Id.

\(^{85}\) § 403.906.
c. Primary business street address

d. NPI

e. State professional license number for at least one state where the physician maintains a license, and the state(s) in which the license is held

(3) Whether the ownership or investment interest is held by the physician, or an immediate family member of the physician

(4) Dollar amount invested

(5) Value and terms of each ownership or investment interest

(6) Any payments or other transfers of value provided to the physician owner or investor, including:

a. Amount of payment or other transfer of value in U.S. dollars

b. Date of payment or other transfer of value

c. Form of payment or other transfer of value

d. Nature of payment or other transfer of value

e. Name(s) of related covered drugs, devices, biologicals, or medical supplies

f. NDCs of related covered drugs and biologicals, if any

g. Name of entity that received the payment or other transfer of value, if not provided to the physician owner or investor directly

h. Statement providing additional context for the payment or other transfer of value (optional).

To avoid duplicative reporting, applicable manufacturers should report the payments or other transfers of value provided to physician owners or investors in the report for payments and other transfers of value, and should note that the covered recipient receiving the payment or other transfers of value is a physician owner or investor.\(^{86}\) Additionally, an individual may be both a covered recipient and a physician

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\(^{86}\) 78 Fed. Reg. at 9495.
owner or investor. An applicable manufacturer should only report a payment or other transfer of value once, regardless of whether it is required to be reported as a payment or other transfer of value, or ownership interest.  

**III. REPORT SUBMISSION AND CORRECTION**

A. **Submissions**

In its proposal, CMS had recommended, but not required, a pre-submission review whereby applicable manufacturers and GPOs would provide each covered recipient or physician owner or investor with the information the manufacturer or GPO intended to submit to CMS. In the preamble to the final rule, CMS stated that while it agrees that a pre-submission review may be helpful, it will not administer or manage a pre-submission review process and will not make it mandatory. CMS recommends that applicable manufacturers and GPOs voluntarily provide covered recipients the opportunity to review the information prior to submission to CMS, but since there is a post-submission review period, does not believe the additional burden of a pre-submission review process is essential.  

Applicable manufacturers and GPOs must submit their reports for the preceding calendar year electronically to CMS by March 31, 2014, and by the 90th day of each calendar year thereafter.

Only applicable manufacturers that made a payment to a covered recipient or had a physician owner or investor in the previous calendar year need to register and submit a

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87 *Id.* at 9496.

88 *Id.*

89 § 403.908(a).
report to CMS. Similarly, only applicable GPOs with a physician owner or investor are required to submit a report.\textsuperscript{90} In other words, even if an entity meets the definition of applicable manufacturer or applicable GPO, it need not register or submit a report if it has no payments or other transfers of value to report.\textsuperscript{91}

Applicable manufacturers and applicable GPOs that are required to report must register with CMS within 90 days after the end of the calendar year for which a report is required (i.e., on or before the due date of the report).\textsuperscript{92} Applicable manufacturers and GPOs must provide two points of contact when registering.\textsuperscript{93}

An applicable manufacturer under common ownership with separate entities that are also applicable manufacturers may, but are not required to, file a consolidated report of all payments or other transfers of value, and physician ownership or investment interests, for all entities.\textsuperscript{94} All applicable manufacturers with payments or other transfers of value to report must register individually, even if they intend to be part of a consolidated report submitted by another applicable manufacturer. Applicable manufacturers submitting data as part of a consolidated report to be submitted by another manufacturer may indicate during registration that they intend to be part of the report submitted by another manufacturer. The entity submitting the consolidated report must indicate all the manufacturers for which it is reporting.\textsuperscript{95}

\textsuperscript{90} § 403.908(b).

\textsuperscript{91} 78 Fed. Reg. at 9496-9497.

\textsuperscript{92} § 403.908(c)(2).

\textsuperscript{93} § 403.908(c)(3).

\textsuperscript{94} § 403.908(d).

\textsuperscript{95} § 403.908(d)(1)(iii).
CMS finalized the requirement for an authorized representative to submit a signed attestation at the time of data submission certifying to the truthfulness, accuracy, and completeness of the data submitted to the best of the signer’s knowledge and belief.96 The proposed rule required the attestation to be signed by the chief executive officer, chief financial officer, or chief compliance officer. However, CMS did not wish to confine applicable manufacturers or GPOs with regard to who must attest, so the final rule allows other officers to attest, as designated by the company.97 An entity submitting a consolidated report must attest on behalf of itself and each of the other applicable manufacturers included in the report.98

While the attestation must be provided at the time of data submission, it must also be provided any time the data is changed or updated. CMS will consider the most recent data for which there is an attestation to be the official data; data without an attestation will not be considered an official submission.99 For an applicable manufacturer with payments or other transfers of value to report, if covered products represent less than ten percent of total (gross) revenue for the preceding year (see section I.A.5, above), the attestation must indicate that fact.100

In response to comments about file format, CMS agreed that it should provide applicable manufacturers and applicable GPOs with reporting templates and more details on reporting, but believes this should not be done by regulation, in order to allow the

96 § 403.908(e).
97 § 403.908(e).
98 § 403.908(e).
100 Id.
agency more flexibility in responding to stakeholder feedback.\footnote{Id. at 9497.} CMS noted that if it intends to make changes to the reporting template or other reporting details, it will provide that information at least 90 days prior to the first day of data collection for the next reporting year.\footnote{Id.} CMS also stated that it will not grant submission extensions, and any late data will be considered a failure to report, which may be subject to penalties.\footnote{Id.}

B. Corrections and Disputes

The statute requires that, following submission of the reports, CMS must provide applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors with the opportunity to review the data for at least 45 days prior to publication on the public website. CMS finalized that it will notify physicians and teaching hospitals that have registered with CMS ahead of time that the information is ready for review using email list serves, online postings, and email.\footnote{§ 403.908(g)(2).} Though registration by these entities is not mandatory, CMS recommends that all covered recipients and physician owners or investors register so they can review the data attributed to them.\footnote{78 Fed. Reg. at 9499.} CMS will also work with physician professional societies and provide the information to applicable manufacturers and GPOs so they may voluntarily provide this information to covered recipients and physician owners or investors.\footnote{Id.}
Though some commenters requested a longer review and correction period, CMS finalized a 45-day period, during which covered recipients and physician owners and investors may register and sign in to the secure CMS website to review the data submitted.\(^\text{107}\) If a covered recipient or physician owner or investor disagrees with the data, he can initiate a dispute, and applicable manufacturers or GPOs may begin resolving the dispute and correcting the data.\(^\text{108}\) After the end of the 45-day review and correction period, applicable manufacturers and GPOs will have an additional 15 days to correct data for purposes of resolving disputes, after which they may submit, and provide attestation for, the updated data to CMS to finalize the submission.\(^\text{109}\) Payments or other transfers of value or ownership or investment interests that cannot be resolved by the end of the 15-day resolution period will be marked as “disputed,” but the applicable manufacturer’s or GPO’s most recent attested data subject to the dispute will be the only information published.\(^\text{110}\)

The 45-day review and correction period and 15-day dispute resolution period will not be the only opportunities to dispute the contents of the public website. CMS will allow physicians and teaching hospitals, and physician owners and investors, the opportunity to sign in to the system to review or dispute officially submitted and attested transactions any time during the year. Any disputes resolved outside the 45- and 15-day time periods, however, will not be reflected on the public website until the next update of the data.\(^\text{111}\)

\(^{107}\) § 403.908(g)(1).

\(^{108}\) § 403.908(g)(3)(iv).

\(^{109}\) § 403.908(g)(4).

\(^{110}\) § 403.908(g)(4)(iii).

\(^{111}\) 78 Fed. Reg. at 9503.
IV. CIVIL MONETARY PENALTIES

Section 1128G(b) of the SSA authorizes CMS to impose civil monetary penalties (CMPs) for any failure to report the required information in a timely manner. CMS finalized that a CMP may be imposed for a failure to submit a report in a timely, accurate, or complete manner. If an applicable manufacturer or applicable GPO fails to submit the required information, it may be subject to CMPs of not less than $1,000, but not more than $10,000, for each payment or ownership or investment interest not reported. The maximum penalty that can be assessed for failure to report is $150,000 each year.

For knowing failures, an applicable manufacturer or applicable GPO will be subject to penalties of not less than $10,000, but not more than $100,000, for each payment or ownership or investment interest not reported. The maximum penalty for a knowing failure to report is $1,000,000 each year. The CMPs imposed on each applicable manufacturer or GPO are aggregated separately, and subject to separate aggregate totals for failures to report and knowing failures to report, with a maximum combined total of $1,150,000.

The factors that CMS will consider in determining the amount of the CMP include, but are not limited to, the following:

1. The length of time the applicable manufacturer or GPO failed to report,

   § 403.912(a)(1).
   § 403.912(a)(2).
   § 403.912(b)(1).
   § 403.912(b)(2).
   § 403.912(c).
2. The amount of payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer or applicable GPO failed to report,
3. The level of culpability,
4. The nature and amount of information reported in error, and
5. The degree of diligence exercised in correcting information reported in error.\textsuperscript{117}

For consolidated reports, the applicable manufacturer that submits the consolidated report will be required to attest on behalf of all the entities included in the consolidated report, and will therefore be subject to the maximum penalties for each individual applicable manufacturer included in the report. The submitter of the consolidated report could therefore be subject to a CMP greater than $1,000,000 depending on the violations of the applicable manufacturers for whom it submitted the report and attested as to the data.\textsuperscript{118}

HHS, CMS, OIG, or their designees have the right to audit or inspect applicable manufacturers or applicable GPOs for their compliance with the timely, complete, and accurate submission of the required information.\textsuperscript{119} In order to facilitate the auditing and inspection process, applicable manufacturers and applicable GPOs must maintain books, records, and documents to enable an audit or inspection for a period of at least five years from the date the payment or other transfer of value, or ownership or investment interest is published on the website.\textsuperscript{120}

\textsuperscript{117} § 403.912(d).
\textsuperscript{118} 78 Fed. Reg. at 9507.
\textsuperscript{119} § 403.912(e)(2).
\textsuperscript{120} § 403.912(e)(1).
V. CMS WEBSITE

The statute requires CMS to publish the data collected from applicable manufacturers and GPOs on a publicly available website by June 30 of each year. Due to the timing of the final rule, the first publication will be in September 2014 for data collected in 2013.\textsuperscript{121}

In the proposed rule, CMS asked for stakeholder feedback on the public website. In the preamble to the final rule, CMS stated that it plans to engage stakeholders about the content of the website, since it recognizes that stakeholders and the public must be part of the website development process.\textsuperscript{122} To maintain flexibility over the design of the website, CMS does not address the content or structure of the website in the final rule.\textsuperscript{123} However, the preamble does set out the data elements that will be included in the website.\textsuperscript{124}

In response to comments suggesting that the website include information about the benefits of relationships between manufacturers and physicians and teaching hospitals, CMS states in the preamble that it will ensure that the website “accurately and completely describes the nature of relationships between physicians and teaching hospitals, and the industry, including an explanation of beneficial interactions,” and that the website will clearly state that disclosure on the website “does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing.”\textsuperscript{125}

\textsuperscript{121} 78 Fed. Reg. at 9503.

\textsuperscript{122} Id.

\textsuperscript{123} Id.

\textsuperscript{124} Id. at 9504.

\textsuperscript{125} Id. at 9503-9504.
VI. ANNUAL REPORTS

CMS must submit annual reports to Congress and the states. The annual report is due annually to Congress on April 1, and must include aggregated information on each applicable manufacturer and GPO submitted during the prior year, as well as any enforcement actions taken and penalties paid. Because the data is not submitted until the end of March each year, the data for that year will not be ready for the April 1 report, so CMS will report to Congress information submitted for the preceding year.\(^\text{126}\)

The reports to the states are due annually by June 30 of each year. Since these are due later in the year than the congressional reports, they will include data collected during the previous calendar year which was submitted in the current year. The state reports will be state-specific.\(^\text{127}\)

VII. RELATION TO STATE LAWS

Section 1128G(d)(3) of the SSA preempts any state or local laws requiring reporting of the same type of information regarding payments made by applicable manufacturers to covered recipients. However, this does not prevent a state from collecting this information for public health surveillance, investigation, or other public health purposes or health oversight.\(^\text{128}\) Since all state payment reporting conceivably could be justified on public health grounds, the preamble clarifies that the public health

\(^{126}\) Id. at 9508.

\(^{127}\) Id.

\(^{128}\) § 403.914(a).
goal must be one other than transparency in order for the state reporting to avoid preemption.\textsuperscript{129}

In the preamble, CMS clarifies that state and local governments may require reporting of information other than that required under section 1128G(a)(1).\textsuperscript{130} The additional information may include other types of information (except payments that fall below the $10 individual or $100 aggregate threshold), or payments to health care providers other than physicians and teaching hospitals.

\textbf{VIII. IMPLEMENTATION DATE}

Applicable manufacturers and applicable GPOs must begin to collect the required data on August 1, 2013, and report the 2013 data to CMS by March 31, 2014.\textsuperscript{131}

\textsuperscript{129} 78 Fed. Reg. at 9509.
\textsuperscript{130} Id. at 9508-9509.
\textsuperscript{131} Id. at 9458.