

Tab 1-21



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date reported by the manufacturer. This refinement may not capture all outlier AMPs that would offset the availability of drugs at the FUL price. It is possible that a product that is not discontinued may be available on a limited basis at a very low price. As a further safeguard to ensure that a drug is nationally available at the FUL price and that a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs, we proposed to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug. That is to say, that the AMP of the lowest priced therapeutically equivalent drug will be used to establish the FUL, except in cases where this AMP is more than 70 percent below the second lowest AMP. In those cases, the second lowest AMP will be used in the FUL calculation. We proposed to use this percentage calculation as a benchmark to prevent an outlier price from determining the FUL, but invited comments as to whether this percentage is an appropriate measure to use. We did consider other options, such as 60 percent below the next highest AMP so that at least drugs of two different manufacturers would be in the FULs group, but we were concerned that this percentage was insufficient to encourage competition where the cost of a particular drug was dropping rapidly. We also considered a test of a drug priced 90 percent below the next lowest priced drug, in line with how we look on nominal prices, as an indicator that the manufacturer was offering this drug on a not-for-profit basis. However, we noted that nominal price relates to best price for some sales and it is unlikely a manufacturer would sell all of its drugs at this price. We welcomed suggestions about other means to address outliers and whether outliers should be addressed at all.

We proposed an exception to the 30 percent carve-out policy when the FUL group only includes the innovator single source drug and the first new generic in the market, including an authorized generic. In this event, we would not apply the 30-percent rule as we believe the DRA intends that a FUL be set when new generic drugs become generally available so as to encourage greater utilization of a generic drug when the price is set less than its brand name counterpart.

We invited comments from the public on all issues set forth in this subpart. We invited suggestions on how best to accomplish the goal of ensuring that the use of AMP in calculating the FUL will

ensure that a drug is available nationally at the FUL price. We asked commenters to please submit data supporting their proposals when available. Upper Limits for Drugs Furnished as Part of Services (§ 447.516)

We proposed that the existing § 447.334 be redesignated as a new § 447.516.

State Plan Requirements, Findings and Assurances (§ 447.518)

We proposed that the existing § 447.333 be redesignated as a new § 447.518.

FFP: Conditions Relating to Physician-Administered Drugs (§ 447.520)

Prior to the DRA, many States did not collect rebates on physician-administered drugs when they were not identified by NDC number because the NDC number is necessary for States to bill manufacturers for rebates. In its report, "Medicaid Rebates for Physician Administered Drugs," (April 2004, OEI-03-02-00660), the OIG reported that, by 2003, 24 States either required providers to bill using NDC numbers or identified NDC numbers using a Healthcare Common Procedure Coding System (HCPCS)-to-NDC crosswalk for physician-administered drugs in order to collect rebates. Four of the 24 States were able to collect rebates for all physician-administered drugs, both single source and multiple source drugs (one State only collected these rebates from targeted providers). Section 6002 of the DRA added sections 1927(a)(7) and 1903(i)(10)(C) to the Act to require that States collect rebates on certain physician-administered drugs in order for FFP to be available for these drugs.

Section 1927(a)(7)(A) of the Act requires that, effective January 1, 2006, in order for FFP to be available, States must require the submission of utilization data for single source physician-administered drugs using HCPCS codes or NDC numbers. (HCPCS codes are numeric and alpha-numeric codes assigned by CMS to every medical or surgical supply, service, orthotic, prosthetic and generic or brand name drug for the purpose of reporting healthcare transactions for claims billing. Physician-administered drugs are assigned alpha-numeric HCPCS codes, and are commonly referred to as J-codes. However, physician-administered drugs are also coded using other letters of the alphabet. For this reason, we referred to the coding system, HCPCS, as opposed to one set of alpha-numeric codes in our discussion of section 6002 requirements.) If States collect HCPCS codes for single source drugs, they can

crosswalk these codes to NDC numbers because most HCPCS codes for single source drugs include only one NDC in order to collect rebates.

Section 1927(a)(7)(C) of the Act requires that, beginning January 1, 2007, States must provide for the submission of claims data with respect to physician-administered drugs (both single source and multiple source drugs) using NDC numbers, unless the Secretary specifies that an alternative coding system can be used. The Secretary did not propose to specify an alternative coding system because we believe that NDC numbers are well established in the medical community and provide States the most useful information to collect rebates.

Section 1927(a)(7)(B) of the Act requires the Secretary, by January 1, 2007, to publish a list of the 20 multiple source physician-administered drugs with the highest dollar volume dispensed under the Medicaid Program. We proposed that the list be developed by the Secretary using data from the Medicaid Statistical Information System and published on the CMS Web site.

Section 1927(a)(7)(B)(ii) of the Act (when read with other DRA amendments) requires that, effective January 1, 2008, in order for FFP to be available, States must provide for the submission of claims for physician-administered multiple source drugs using NDC numbers for those drugs with the highest dollar volume listed by the Secretary.

We proposed, for the purpose of this section, that the term "physician-administered drugs" be defined as covered outpatient drugs under section 1927(k)(2) of the Act (many are also covered by Medicare Part B) that are typically furnished incident to a physician's service. These drugs are usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting. Examples include injectables: lupron acetate for depot suspension (primarily used to treat prostate cancer), epoetin alpha (injectable drug primarily used to treat cancer), anti-emetic drugs (injectable drug primarily used to treat nausea resulting from chemotherapy) intravenous drugs primarily used to treat cancer (paclitaxel and docetaxel), infliximab primarily used to treat rheumatoid arthritis, and rituximab primarily used to treat non-Hodgkin's lymphoma. We believed that some oral self-administered drugs (administered in an outpatient clinical setting), such as oral anti-cancer drugs, oral anti-emetic drugs should also be included in the designation of physician-administered

drugs consistent with Part B policy and sections 1861(s)(2)(Q) and (T) of the Act.

Section 1927(a)(7)(D) of the Act allows the Secretary to grant States extensions if they need additional time to implement or modify reporting systems to comply with this section. We did not propose any criteria for reviewing these extension requests as we expected that most, if not all States would be able to meet the statutory deadlines for collection of NDC numbers on claims. Most States are already collecting rebates for single source drugs that are provided in a physician's office. For multiple source drugs, the States have nearly two years following enactment of the DRA before FFP would be denied for the 20 multiple source drugs specified by the Secretary as having the highest dollar volume.

We expected that States would require physicians to submit all claims using NDC numbers, as using multiple billing systems would be burdensome for physicians and States. This would also advantage States because rebates would be collectible on all physician-administered drugs.

For States not currently billing manufacturers for rebates on single source drugs, we believed that the Medicare Part B crosswalk may be helpful to crosswalk HCPCS codes to NDC numbers. This crosswalk may be found on the CMS Web site at http://new.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp.

To implement the provisions set forth in section 6002, we propose a new § 447.520. In § 447.520(a), we proposed to require States to require that claims for physician-administered drugs be submitted using codes that identify the drugs sufficiently to bill a manufacturer for rebates in order for the State to receive FFP. In § 447.520(b), we proposed requiring States to require providers to submit claims using NDC numbers. In § 447.520(c), we proposed allowing States that require additional time to comply with the requirements of this section to apply to the Secretary for an extension.

III. Analysis of and Responses to Public Comments

We received over 1,600 timely items of correspondence that addressed the issues in the proposed rule. We received comments from pharmacists and other health care providers, drug manufacturers, membership organizations, law firms, PBMs, consultants, State agencies, members of Congress, and individuals. A summary

of the major issues and our responses follow.

General Comments

We received many comments expressing general support for the provisions of the proposed rule. One commenter specifically indicated support for Federal efforts that are designed to positively affect the affordability of and access to prescription drugs and healthcare professionals. Other commenters indicated support for CMS' efforts to clarify the definitions of significant terms as well as the treatment of various types of sales and prices in manufacturer calculations.

Comment: Commenters asked CMS to explain how we will reconcile the national rebate agreement with this final rule, which substantially changes a number of the definitions and requirements of the agreement. One commenter asked CMS to specify that it will not incorporate into a revised national rebate agreement any definitions or requirements until such provisions have been subject to notice-and-comment rulemaking.

Response: The national rebate agreement provides that manufacturers should comply with the Medicaid rebate statute, any amendments to that statute, and regulations issued by the Secretary to implement the statute. We will consider revising the national rebate agreement in accordance with applicable Federal statutes and regulations.

Effective Date

Comment: Many commenters asked CMS to clarify that the provisions of this final rule will be applied prospectively. One commenter specifically asked for clarification of the effective date of the provision regarding the treatment of Medicaid sales in AMP. Another commenter expressed concern that CMS should have published the proposed rule by September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of the changes in the Medicaid Program.

Response: In this final rule, we are bringing together existing and new regulatory requirements in one cohesive subpart. Unless otherwise indicated, these regulations are effective on October 1, 2007. However, this rule is not designed to delay the effective date with respect to statutory provisions, regulations or policies that are already in effect. Those existing requirements that remain unchanged in this final rule will continue in force. In addition, to the extent that this rule addresses

previous policies already established by the Agency, those policies will remain in effect. Further, the DRA provided specific effective dates for certain provisions as noted in the preamble to the proposed rule.

Comment: Many commenters asked us to consider delaying implementation of the final rule. Several commenters suggested that we delay the overall effective date of this final rule at least six months from the date of publication in order to provide manufacturers with necessary time to revise their systems and retrain personnel on the requirements of this final rule. One commenter noted that government pricing system vendors will need between six months to one year after the effective date of this final rule to code, implement and test the required computer changes.

Other commenters suggested a delay of four quarters for the entire rule. One commenter suggested we delay finalizing the rule until more detailed information regarding AMP and the established FUL is made available to the pharmacy industry; another commenter suggested a delay of 90 days after the release of the new FUL source file. Another commenter suggested a 180-day compliance period followed by a 90-day testing period, during which time the AMP may only be used for research and verification purposes only.

A few commenters specifically asked that we delay the implementation of the requirement that manufacturers submit a base date AMP. Another commenter noted that the practical implication of treating inpatient and outpatient hospital sales differently for AMP purposes would mean that hospital contracts for the purchase of prescription drugs would need to be renegotiated, which could necessitate a delay in the implementation of the AMP rule for six months to a year.

Response: The DRA provides specific timeframes for the implementation of many of the major provisions addressed in this final rule. Because the DRA was signed into law on February 8, 2006, we believe there was sufficient time for affected parties to prepare for the implementation of these provisions. In addition, CMS issued guidance to States and manufacturers in December, 2006 to address many of the details pertaining to the drug provisions in the DRA. Accordingly, we are not convinced that there is a compelling reason to delay implementation of the provisions of this final rule beyond the October 1, 2007, effective date.

Comment: One commenter recommended that CMS do more to educate Medicare participating

effective and States would then have an opportunity to analyze AMPs, as revised by the DRA, and FULs. It will also give CMS an opportunity to receive further comments based on a broader analysis of the data. CMS will accept comments on the outlier (and as discussed previously on the AMP) policy for a period of 180 days from the date of publication of this final rule in the **Federal Register**.

Comment: Several commenters strongly recommended that, in lieu of an outlier, CMS should set FULs based on the weighted average AMP of the therapeutically equivalent products available in the market. One commenter stated that this would avoid regional pricing that may not be widely available for a specific product, "fire sale" pricing on short-dated products, and prices that are not sustainable over a consistent period of time.

Response: We disagree. The DRA provides, effective January 1, 2007, that the upper limit for multiple source drugs be established at 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

Comment: One commenter stated that if the calculated FUL exceeds the AWP of the innovator multiple source drug, or exceeds the innovator multiple source drug's AMP by 25 percent or more, CMS should not publish a FUL for that ingredient group.

Response: We do not agree that a FUL should not be set if it exceeds the AWP for the innovator multiple source drug. There is no basis, given the statutory amendments, to calculate a FUL using an AWP standard. We agree that States may not find a FUL useful if it exceeds the AMP of the innovator multiple source drug by 25 percent; however, we do not believe we should make an exception in this instance. The FUL is designed to be an aggregate upper limit, not necessarily a payment rate for drugs.

Terminated Drugs

Comment: Some commenters submitted comments regarding the use of a terminated drug to set the FUL. One commenter expressed concern that the proposed rule does not take into account that an AMP may be from a terminated product. One commenter stated that CMS should provide notification of terminated NDCs associated with the establishment of FULs, so that State Medicaid agencies do not continue to reimburse for a terminated drug. One commenter stated that CMS should clarify the meaning of "terminated."

Response: The proposed rule would exclude terminated NDCs from consideration when setting a FUL beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS. We are retaining this provision in the final rule. A FUL reimbursement applies to all drugs within an ingredient group, including drugs that are being terminated by the manufacturer, but still being produced by a manufacturer. However, a terminated NDC would not be used to set the FUL. We continue to define a terminated drug according to the reason the product is being discontinued. If it is being pulled from the shelf immediately due to a health or safety reason, whether it is by FDA or labeler directive, the termination date is the date removed. If, however, it is being replaced by an improved version, or discontinued, the termination date is the shelf life of the last batch sold.

Upper Limits for Drugs Furnished as Part of Services (§ 447.516)

Comment: One commenter pointed out that while the FUL will be revised monthly, managed care capitation arrangements are negotiated for longer periods of time, making it difficult for State Medicaid Agencies to comply with frequent FUL changes when setting capitation rates. Another commenter stated that the final rule should be amended to exclude FULs from capitation arrangements to address this concern.

Response: States will need to consider possible fluctuations in FULs when negotiating future MCO contracts and modify current contracts, if necessary, to address any revisions needed to capitation rates as a result of monthly FUL changes. Also, to note the FULs are designed to be aggregate upper limits, and do not represent individual payments for drugs. In accordance with § 447.516, the upper limits for payment for prescribed drugs also apply to payment for drugs provided under prepaid capitation arrangements. CMS has not changed this requirement.

State Plan Requirements, Findings and Assurances (§ 447.518)

Comment: One commenter requested that CMS insert language in the final rule that would require States to consult with Tribes in the development of any SPA which would modify existing payment methodologies for prescription drug reimbursement. This would allow each Tribe the opportunity to work with its State to assess local impacts prior to submission of SPAs.

Response: A State Medicaid Director letter dated November 9, 2006 was sent

encouraging States to consult with Tribes in open, good faith dialogue, on the DRA provisions that have the potential to impact Tribes and American Indian and Alaska Native Medicaid beneficiaries. The letter stated that it is important to maintain ongoing communication between States and Tribes in the redesign of Medicaid Programs and services.

Comment: One commenter requested that CMS insert language in the final rule to encourage States to maintain their current level/type of reimbursement and filling fees to Tribal and IHS pharmacies. Tribal and IHS providers should be explicitly recognized as essential safety net pharmacies.

Response: We appreciate the comment and will take this suggestion into consideration as we consider revisions to State payment rates. In accordance with longstanding policy, we believe that States should have the flexibility to establish payment rates and reasonable dispensing fees, consistent with the upper limits and standards set forth in our regulations.

Comment: One commenter believed that the SPA process must be more deliberative and transparent than the process that has been used to date by States to make changes in their payment methodologies. States need to be more diligent and transparent in providing public notice about reimbursement methodologies and substantiating the impact that the changes could have on Medicaid beneficiaries' access to community retail pharmacies.

Response: We disagree with the commenter. States must follow Federal regulations at 42 CFR 430 subpart B for all State plans.

Comment: One commenter suggested to amend § 447.518(b)(1) by adding another § 447.518(b)(1)(iii), which would say, "in the aggregate, the dispensing fees paid to pharmacies cover the costs described in § 447.502 and are designed to encourage the utilization of multiple source drugs where appropriate."

Response: We disagree with the commenter. In accordance with longstanding policy, we believe that States should have the flexibility to establish payment rates and reasonable dispensing fees, consistent with the upper limits and standards set forth in our regulations.

FFP: Conditions Relating to Physician-Administered Drugs (§ 447.520)

We received many comments regarding the requirement that State Medicaid Agencies provide for the submission of NDCs on claims for

physician-administered drugs, as discussed below:

Comment: Several commenters stated that CMS has failed to define outpatient drugs that are physician-administered as required by the statute. The commenter further stated that CMS is incorrectly interpreting the law by including drugs administered in the outpatient hospital setting.

Response: In light of the definition of covered outpatient drug provided in section 1927 of the Act, we have chosen not to define what is meant by a covered outpatient drug that is administered by a physician. We believe that the DRA amendments to section 1927 of the Act were intended to emphasize that where covered outpatient drugs are administered by a physician and separately billed to Medicaid, States are required to collect rebates from manufacturers for these drugs. The law requires that States obtain information on the claims forms that will allow them to bill manufacturers for rebates for specific covered outpatient drugs in accordance with section 1927 of the Act.

Comment: A few commenters stated that the statute permits the use of J-codes as well as NDCs.

Response: The statute allows the Secretary to specify the required codes. We proposed to allow J-codes, also known as HCPCS codes, to be used beginning January 1, 2006 for single source physician-administered drugs. We also specified that the NDC be required for single source drugs and the 20 multiple source drugs identified by the Secretary beginning January 1, 2007. We are finalizing these requirements in this final rule.

Comment: Several commenters asked that CMS provide a list of NDCs within the J series of HCPCS codes that are subject to rebates under the Medicaid Drug Rebate Program.

Response: At this time, CMS does not intend to publish a list of NDCs for each physician-administered drug that is subject to Medicaid rebates, as such a list would be quite expansive. However, CMS provides monthly files of drugs of manufacturers that have a national rebate agreement under the Medicaid Program. CMS also maintains a list of NDCs within HCPCS that can be found on our Web site at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2007aspfiles.asp#TopOfPage.

Comment: One commenter asked that CMS revise the HCPCS J-code crosswalk to NDCs on our Web site to identify: (1) physician-administered drugs not routinely covered by Medicare but covered by Medicaid, (2) the sole source and 20 multiple source drugs for which

NDCs must be collected, and (3) NDCs for manufacturers that participate in the Medicaid Drug Rebate Program.

Response: At this time, we do not intend to revise the HCPCS crosswalk to identify drugs not routinely covered by Medicare but covered by the Medicaid Drug Rebate Program. However, the publicly available AMP pricing data will be listed with NDCs which will indicate manufacturers participating in the Medicaid Drug Rebate Program as well as the products covered by the program. The list of the top 20 multiple source physician-administered drugs are posted on CMS' Web site at <http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Top20PhysicianAdministered.pdf>.

Comment: Several commenters asked that CMS clarify the prospective nature of the proposed definition of physician-administered drug.

Response: The DRA requirement that States collect information sufficient to bill for rebates on single source drugs was effective January 1, 2006 and States must bill for rebates to collect a Federal match on these drugs. For single source physician-administered drugs and the 20 specified multiple source physician-administered drugs, States must collect NDCs beginning January 1, 2007. However, Federal match remains available until January 1, 2008, at which time we expect that States will be in compliance with this requirement. We would note that the requirement for States to submit utilization data to collect rebates on covered outpatient drugs in section 1927(b) of the Act predates the DRA requirements and inasmuch as physician-administered drugs are covered outpatient drugs, we believe that the January 1, 2006 effective date was reasonable. The DRA emphasized physician-administered drugs because these drugs historically have been billed by providers in such a way that prevented States from collecting rebates for these drugs.

Comment: Many commenters expressed the opinion that manufacturer rebate liability should be proportional to State Medicaid expenditures when Medicaid is the secondary payer. They contended that this is more consistent with the overall intent of the rebate program to reduce the cost of drugs to Medicaid and to ensure Medicaid the best price provided to other purchasers. Other commenters believed that CMS' position concerning the intent of the Medicaid statute that full rebates are due when Medicaid pays any amount of the claim is incorrect and is procedurally invalid because this policy was not established through formal notice-and-comment rulemaking.

Another commenter wished CMS to continue with the historical practice of having Medicaid claim rebates on the total amount paid for the drug by all parties.

Response: We disagree that the rebate should be proportional to the amount of the claim paid by Medicaid. Neither the law nor the national rebate agreement makes provision to reduce the rebate liability based on the amount of payment made by the Medicaid Program. Rather, the law provides formulas for rebate payments for single source, innovator multiple source, and noninnovator multiple source drugs that are used when Medicaid makes payment for a drug. This has been the consistent policy position of the Agency since the start of the Medicaid Drug Rebate Program.

Comment: One commenter said that CMS should not deny Federal matching funds for physician-administered drugs not covered by the national rebate agreement.

Response: The statute requires drug manufacturers to participate in the Medicaid Drug Rebate Program in order for their drugs to be covered by Medicaid. We recognize that States may not always be aware of what drug was administered when a bill is submitted using a HCPCS code. However, when the law requires billing with an NDC, a State Medicaid Agency cannot knowingly pay that claim and collect the Federal match.

Comment: Some commenters said that the requirement that outpatient hospitals record NDCs would have a negative impact on patient safety because it would disrupt the workflow for dispensing drugs and divert limited staff from accurate dispensing.

Response: We have no reason to believe that patient safety will be affected by this requirement.

Comment: One commenter stated the belief that contrast agents, typically used during hospital-based radiological procedures, are excluded from Medicaid rebates.

Response: Only physician-administered drugs that are separately billed to Medicaid as covered outpatient drugs will be considered physician-administered drugs for the purposes of this rule. If the contrast agents are not billed to Medicaid as outpatient drugs, they would not be considered physician-administered drugs for purposes of this provision.

Comment: One commenter stated that the regulation should exempt drugs administered in an emergency room from this provision because physicians should not need to concern themselves with whether the patient is a Medicaid

beneficiary and because the physician does not know at the time drugs are administered if the patient will be admitted or sent home.

Response: Drugs administered incident to an emergency room service that are billed separately as covered outpatient drugs, as defined by section 1927(k)(2) of the Act, are covered under the Medicaid Drug Rebate Program and must be billed using the NDC in order for States to collect the Federal match. Drugs that are billed as part of an emergency room service as described in section 1927(k)(3) of the Act, where the cost of the drug is bundled within the cost of the service, are not covered by the Medicaid Drug Rebate Program.

Comment: One commenter asked if HCPCS will be assigned to drugs that do not currently have them.

Response: We do not plan to assign HCPCS to drugs as the provisions addressed in this rule require the submission of NDCs on claims when billing Medicaid for physician-administered drugs.

Comment: One commenter asked CMS to clarify in the final rule that claims for physician-administered drugs must meet all covered outpatient drug requirements, specifically, that the drug must be subject to a Medicaid rebate, not have a termination date prior to the date of service, and not be a drug with a DESI value of five or six.

Response: The commenter is correct that all requirements for Medicaid drug coverage apply to physician-administered drugs.

Comment: Several commenters believe that CMS went beyond congressional intent by including outpatient hospitals and clinics in the requirement for States to collect NDC-level information on pharmacy claims. Commenters stated that the OIG report on this topic addressed only drugs administered in physicians' offices and that this report was the impetus for the legislation.

Response: We base our interpretation on the language in the statute which does not differentiate between providers in requiring that States collect information sufficient to bill for rebates for covered outpatient drugs under section 1927(k)(3) of the Act. To the extent that providers bill for covered outpatient physician-administered drugs separately; that is, the cost of the drug administered is a separate line item from the service provided, we believe that, in accordance with the statute, States should be seeking rebates with respect to such drugs.

Comment: Several commenters wrote that the DRA does not change the existing statute at section 1927(j)(2) of

the Act that exempts from Medicaid drug rebates drugs administered to patients in hospital outpatient clinics and departments.

Response: We agree that the DRA did not change the exclusion of drugs from Medicaid rebates when dispensed in an outpatient hospital setting as long as Medicaid is billed at the hospital's purchasing costs. However, hospitals commonly bill Medicaid without regard to their costs and accept the full reimbursement provided under the Medicaid State plan. When this is the case, drug manufacturers are responsible for paying rebates with respect to those drugs that qualify as covered outpatient drugs under section 1927(k)(3) of the Act.

Comment: One commenter said that rebates should not be collected on hospital outpatient drugs because they are not part of the retail pharmacy class of trade for AMP.

Response: The commenter is not correct in that sales to hospital outpatient departments are considered in the retail pharmacy class of trade and are included in the calculation of AMP at the option of the drug manufacturer, as specified in this final rule. Physician-administered drugs will be excluded from the Medicaid Drug Rebate Program requirements only when hospital outpatient departments have dispensed these drugs using drug formulary systems, and have billed Medicaid at acquisition costs, consistent with section 1927(j)(2) of the Act.

Comment: Several commenters stated that 340B hospitals should not need to forgo receiving discounts on drugs as a result of Medicaid collecting rebates on them and have asked to be exempted from the requirement.

Response: This provision of the DRA does not apply to 340B hospitals that receive discounted drugs and bill Medicaid at the acquisition cost of the drug as determined under the State plan.

Comment: One commenter noted that certain safety-net hospitals receive discounts under the 340B Program and that the law provides that such drugs not be also subject to Medicaid rebates.

Response: We agree with the commenter that drug manufacturer sales to safety-net hospitals under the 340B Program are not subject to Medicaid rebates as long as they are billed to Medicaid at acquisition cost as determined under the State plan.

Comment: One commenter asked that HRSA post the National Provider Identifiers (NPI) of providers who will be billing for physician-administered drugs from 340B covered entities on its

Web site in addition to the NPIs of 340B covered entities.

Response: We are not addressing the concerns of other agencies within the Department of Health and Human Services in this rule. Instead, we suggest that the commenter should address HRSA regarding the posting of NPIs on its Web site.

Comment: One commenter noted that physicians will not know which drugs are included in the Medicaid Drug Rebate Program to be able to administer only those drugs to Medicaid patients. Several commenters noted that physicians need to know which manufacturers participate in the Medicaid Drug Rebate Program because drugs of non-participating manufacturers will not be covered by Medicaid.

Response: We understand the commenter's concern and believe that compliance with this provision will depend upon the level of education/coordination provided by States to the provider community regarding the resources available to them. As previously discussed in this rule, AMPs for drugs covered by the Medicaid Drug Rebate Program will be publicly available and listed by NDC on our Web site. We believe that this resource, along with State information, will assist physicians to make informed decisions regarding the list of covered outpatient drugs available under Medicaid.

Comment: Several commenters asked that CMS develop standard literature for physicians to assist in education and outreach about the requirement for including NDCs on bills for Medicaid.

Response: States traditionally are responsible for provider outreach and education. Materials will vary by State based on processes and procedures determined by each State. We believe that States can avoid duplication of effort by working through the National Association of State Medicaid Directors to share materials and best practices concerning this new requirement.

Comment: One commenter asked CMS to develop a form for hospitals to use to bill States with NDCs because the UB04 billing form does not allow for the inclusion of NDCs. The commenter believed this would be more efficient than each State developing its own form.

Response: CMS would be happy to work with States if they wish to develop a model form.

Comment: A few commenters asked that CMS develop a standard UB04 form that allows for the reporting of the NDC quantity and unit of measure.

Response: CMS cannot specify what is included on the UB04 form. The

National Uniform Billing Committee determines the content of the form. Both CMS and State Medicaid Agencies are represented on this committee and need to work together to establish the need for any changes to the form and to obtain approval for the changes.

Comment: A few commenters noted that not all Durable Medical Equipment Regional Carriers (DMERC) pass through the NDC to the Medicaid agency. The commenters believed that the provision that States allow for the submission of NDCs on claims for physician-administered drugs should also apply to claims for supplies/durable medical equipment for which Medicaid is the secondary payer so that States are able to collect rebates on these claims.

Response: We are aware that not all DMERCs provide the NDC to the Medicaid agency when Medicaid is the secondary payer. We also agree with the commenter that States should be collecting NDCs with respect to separately reimbursed drugs in order to secure rebates under section 1927 of the Act to the extent that they are not included within a bundled rate.

Comment: Several commenters asked that the Secretary use the waiver authority provided by statute to delay the requirement for States to collect NDC-level information from hospitals to provide additional time for them to reconfigure their systems to capture this information.

Response: The statute provides for a hardship waiver for States that require additional time to implement necessary changes to their reporting systems. We will consider States' requests on a case-by-case basis.

Comment: One commenter noted that CMS stated in the proposed rule that we do not expect States to need hardship waivers to postpone the requirement that States collect NDCs on claims for physician-administered drugs by January 2008. The commenter believed that States may find it difficult to meet this date because of other priorities for systems such as the NPI.

Response: We anticipate that many States will have had ample time to meet the January 1, 2008 deadline to comply with the DRA requirements since the DRA was enacted nearly two years prior to that deadline and CMS guidance was given to State Medicaid Directors (SMDL 06-016, <http://www.cms.hhs.gov/smdl/downloads/SMD071106.pdf>) nearly 18 months prior to the deadline.

Comment: One commenter suggested that CMS should re-examine this requirement as it will result in reduced access to care for Medicaid beneficiaries

because of the non-standard billing requirements it imposes.

Response: While we appreciate the comment, we have no reason to believe that the DRA requirement will result in reduced access to care.

Comment: One commenter noted that not all package labels carry the 11-digit NDC which is needed for billing. Some carry a 10-digit number and knowledge of conversion conventions is needed to translate the number to the 11-digit NDC. Another commenter stated an inability of some billing systems to capture the 11-digit NDC. Another commenter noted that the billing units of certain drugs are different from the units used for Medicaid rebates. This will cause confusion and require translation.

Response: As we have previously stated, the education of the provider community by the States will be paramount in ensuring proper billing procedures and the successful implementation of this requirement.

Comment: Several commenters stated that it will be nearly impossible for hospitals to accurately record the NDCs for some drugs. This will occur when drugs are bought in bulk or for cases in which a portion of the drug unit is used. The commenter noted that the difficulty will likely be encountered in instances when multiple drugs are mixed into a treatment "cocktail" and injected or infused into the patient.

Response: We recognize the operational difficulties that may exist for some hospitals but note that the law, as amended by the DRA, makes no exceptions for physician-administered drug claims billed by hospital outpatient departments. This process should be easier when hospitals use the Uniform Product Codes for drugs dispensed.

Comment: One commenter asked that CMS bill manufacturers for rebates directly as opposed to implementing this requirement.

Response: This request is not feasible because States, not CMS, receive claims data necessary to bill manufacturers for rebates. Drug manufacturers do not know which or how much of their drugs are supplied to Medicaid beneficiaries until States submit utilization data as required in section 1927(b)(2) of the Act.

Comment: One commenter suggested that it would be more appropriate for States to obtain detailed NDC information from the drug manufacturers rather than from the community hospitals. The commenter noted that drug manufacturers have access to detailed NDC information and other detailed purchasing information because the drug company

representatives often call the community hospital pharmacy directors to inform them of the number of items hospitals have purchased and how many items are returned for credit.

Response: While we appreciate the commenter's suggestion, this approach would not be operationally feasible because manufacturers would not have utilization data to determine the unit amounts of drugs dispensed to patients.

Comment: One commenter stated that his hospital uses drug dispensing machines located throughout the hospital that have unit dosages of drugs that are not differentiated by NDC. Compliance with this provision would require the hospital to limit each slot on the machine to one NDC, ordering only one NDC for each drug, or billing by unit dose, all of which would be costly and inefficient.

Response: We understand that some hospitals and providers' offices will require systems modifications and changes in dispensing and billing procedures in order to comply with the billing requirements of this provision.

Comment: One commenter asked CMS to specify how compounded drugs should be billed. The commenter suggested that only the NDC and quantity for the NDC that most closely ties to the HCPCS narrative description be required.

Response: We require that NDCs and corresponding quantities for those NDCs for each drug be included on the claims for Medicaid reimbursement.

Comment: One commenter expressed concern that the requirement that providers submit NDCs for physician-administered drugs will create an administrative burden for both the providers and the State Medicaid Agencies. The requirement is impractical with respect to the CMS-1500 because the claims are usually submitted after the drugs are administered making it difficult for the provider to capture the NDC administered to the patient on the claim. Providers will need access to a list of rebatable NDCs and have them in stock, which could result in a delay in administering the necessary medication. The requirement may in fact impair patients' access to necessary medication.

Response: The law requires States to collect rebates on physician-administered covered outpatient drugs in order to receive a Federal match for the cost of the drugs. Because NDCs are required by the manufacturer in order for States to collect rebates on these drugs, providers are required to submit NDCs for physician-administered covered outpatient drugs. We encourage

States to educate the provider community regarding the resources available to them that may assist them in their transition to the requirements. We have no reason to believe that this requirement will have a negative impact on providers or patients' access to medication therapies in an outpatient hospital setting.

Comment: One commenter asked CMS to include a provision in the final rule to encourage States to provide a furnishing fee for blood clotting factors modeled after that provided by Medicare.

Response: State Medicaid programs have sufficient latitude under other provisions of the statute to determine in their State plans how they will reimburse adequately for blood clotting factors. This final rule does not revise options that States have under other provisions of the statute and the State plan to ensure access.

Comment: One commenter noted that the HCPCS crosswalk is only effective for single source drugs where there is a one-to-one relationship between HCPCS code and NDC. There are, in fact, several single source drugs for which there is one J-code but numerous NDCs.

Response: We agree with the commenter that the HCPCS crosswalk is only effective for certain single source drugs and believe that this fact fully supports the need for NDCs to be submitted on claims for physician-administered drugs as set forth in statute and required by this rule.

Comment: Several commenters noted that Part B carriers will need to provide the NDC on the crossover claim for the Medicaid agency to have the information needed to invoice drug manufacturers for rebates. One commenter asked that CMS ensure that Medicare carriers provide NDCs on crossover claims sent to Medicaid. Another commenter noted that the quantity administered for each NDC must also be recorded.

Response: If the NDC is on the electronic claim submitted (CMS-837), the Part B carrier will include it on the crossover claim sent to the Medicaid agency. Although the new CMS-1500 claim form does allow entry of the NDC, the UB04 claim form does not contain a section to capture the NDC. As previously stated, States will need to make it clear that providers must submit claims, complete with the NDC information, to the Medicaid agency. We encourage States to provide educational outreach to providers to inform them of the manner in which the NDCs and corresponding quantities should be recorded on the claims forms as they deem necessary for the accurate

billing of drug manufacturers for rebates.

Comment: One commenter asked us to develop a better remedy for States than rejecting the claim and asking the provider to rebill when an NDC is not provided on a crossover claim. The commenter believes this method is costly, results in delay, is counter to the intent and spirit of HIPAA, and may result in a loss of access for Medicaid beneficiaries to needed drugs.

Response: It is crucial for States to communicate to the provider community the importance of including NDCs on the claims when billing Medicaid for physician-administered drugs. In cases where providers have not included NDCs on claims for physician-administered drugs, we recommend that States coordinate with provider billing offices in any manner that they deem appropriate in order to obtain the NDCs necessary for States to bill manufacturers for rebates as required by the statute.

Comment: One commenter stated that the burden of recording the NDC will fall on clinicians, not support staff. Because Medicaid is the secondary payer for most of these claims, the clinicians may note that the patient has Medicare, which does not require NDCs for billing, and may overlook the Medicaid requirement.

Response: We encourage States through provider education to convey the importance of including the NDCs on the claim in order for States to process claims and payment for the service.

Comment: One commenter believed that the top 20 list of multiple source drugs published on the CMS Web site incorrectly included Factor VII Recombinant and Factor VIII plasma-derived because the commenter did not believe these products meet the statutory definition of multiple source drug.

Response: We agree with the commenter and will remove these products from the top 20 list of multiple source drugs published on our Web site.

Comment: One commenter questioned the inclusiveness of the list of the 20 multiple source physician-administered drugs for which billing with the NDC will be required. The commenter stated that the list should include all NDCs with a particular HCPCS code.

Response: At this time, we do not intend to include all NDCs for a given HCPCS code.

Comment: One commenter asked when the list of 20 drugs will be updated.

Response: We intend to annually review the list of top 20 multiple source

physician-administered drugs on our Web site and update it as necessary.

Comment: One commenter asked that we specify the file format to be used for the submission of claims for physician-administered drugs using NDCs for the top 20 drug list.

Response: States are responsible for determining the file format to be used for the submission of claims. We encourage the States through provider education to inform providers of the correct file format to use when billing for physician-administered drugs using NDCs.

Comment: Several commenters said that State Medicaid Agencies should be required to bear the cost for hospitals to change their systems in order to meet the NDC reporting requirement, as some outpatient hospital departments' systems do not currently capture NDC level utilization data for patient billing.

Response: We do not believe that the law requires Medicaid agencies to pay hospitals for systems modifications that may be necessary to document claims for payment in a manner that would comply with DRA requirements to identify the NDC. States have the option to pay for overhead costs, such as provider billing systems, through dispensing fees to pharmacies or other providers.

Comment: One commenter stated that many State Medicaid processing systems are not designed to capture NDCs on outpatient hospital bills and that implementation of this provision should be delayed until alternate systems can be designed. Another commenter stated that the manual coding of NDCs would come at the expense of staff resources and would disrupt administrative operations.

Response: The timeframe for implementing this provision is set by statute. The DRA was signed into law on February 8, 2006. While States were required to start billing manufacturers for rebates for single source drugs on claims beginning January 1, 2006, States could crosswalk HCPCS to NDCs for these drugs. States continue to have until January 1, 2008 to collect NDCs on the 20 multiple source physician-administered drugs identified by the Secretary before losing Federal match for these drugs. States that cannot meet this deadline can request a waiver from the Secretary to implement this requirement at a later date.

Issues Not Addressed in the Proposed Rule

We received several comments on issues that were not addressed in the proposed rule. A summary of those comments and our responses follow.

customary prompt pay discounts extended to wholesalers. We also clarified that other fees are included in AMP.

In § 447.504(i)(2), we revised the methodology for calculating quarterly AMP to be the weighted average of monthly AMPs in the quarter.

In § 447.505(c)(2), we deleted PBMs from the list of entities included in best price. We also added “PBM rebates, discounts, or other price concessions except mail order purchases” to the list of prices excluded from best price in § 447.505(d)(13).

In § 447.505(c)(12), we removed “manufacturer coupons redeemed by any entity other than the consumer” from the prices included in best price. We also added manufacturer coupons redeemed by an agent, pharmacy or other entity acting on behalf of a manufacturer, as long as the full value of the coupon is passed on to the consumer and the pharmacy, agent or other entity does not receive any price concession, to the list of prices excluded from best price in § 447.505(d)(8).

In § 447.505(d)(3), we limited the SPAP best price exemption to any prices or price concessions provided to designated SPAPs.

In § 447.505(d)(4), we deleted TRICARE from the list of prices excluded from best price.

In § 447.505(e)(2), we clarified the reference to the nominal price provisions in § 447.508.

In § 447.506(a), we removed the phrase “directly or indirectly” from the definition of authorized generic drug.

In § 447.506(b), we revised the initial provision requiring the manufacturer holding title to the original NDA to include the authorized generic sales of the secondary manufacturer in the AMP of the brand drug by specifying that the manufacturer holding title to the original NDA of an authorized generic must include the sales of authorized generics in the AMP of the manufacturer holding title to the original NDA only when the products are sold directly to a wholesaler.

In § 447.506(c), we removed the initial provision that requires the manufacturer holding title to the original NDA to include the sales of the secondary manufacturer in the best price of the brand drug. We added language that would require sales from the manufacturer holding title to the original NDA to the secondary manufacturer to be included in the best price of the manufacturer holding title to the original NDA. We also added language to state that the best price is the lowest price at which the authorized generic drug is sold.

In § 447.510(a)(3), we clarified that customary prompt pay discounts shall be reported for each covered outpatient drug at the 9-digit NDC level. We also clarified that this term includes discounts provided to all wholesalers in the rebate period.

In § 447.510(a)(4), we clarified that nominal prices include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart.

We added § 447.510(b)(2) to specify that manufacturers should not revise AMP when the revision would solely be as a result of data pertaining to lagged price concessions.

In § 447.510(c)(1), we changed the timeframe in which a manufacturer must report base date AMP to CMS from the first full calendar quarter following publication of this final rule to the first four full calendar quarters following publication of this final rule.

In § 447.510(c)(2)(i), we clarified that a manufacturer’s recalculation of base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart, as opposed to § 447.504(e) of the same.

In § 447.510(c)(2)(ii), we added a provision to allow a manufacturer to choose to recalculate base date AMP on a product-by-product basis.

In § 447.510(c)(2)(iii), we added a provision to require manufacturers to use actual and verifiable pricing records in the calculation of base date AMP.

In § 447.510(d)(2), we revised the reg text by removing the reference to § 447.504 and replacing it with the requirement that monthly AMP should be calculated as the weighted average for all the manufacturer’s package sizes of each covered outpatient drug sold by the manufacturer during a month. We also added a requirement that a manufacturer must estimate the impacts of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.

In § 447.510(d)(3), we removed the prohibition against reporting revised monthly AMP and replaced it with a requirement that a manufacturer report revisions to monthly AMP to CMS for a period not to exceed 36 months from the month in which the data were due.

We added § 447.510(d)(4) to prohibit manufacturers from reporting revisions to monthly AMP if the revisions would be solely as a result of data pertaining to lagged price concessions.

We added § 447.510(d)(5) to address monthly AMP reporting requirements for terminated products.

In § 447.510(e)(3), we added a provision to allow pricing reports to be certified by an individual other than a

CEO or CFO who has authority equivalent to a CEO or a CFO.

In § 447.510(e)(4), we allowed pricing reports to be certified by an individual who has the directly delegated authority to perform the certification on behalf of a CEO, a CFO, or an individual with authority equivalent to a CEO or a CFO.

In § 447.512(c)(1), we added language that would allow a physician to indicate that a specific brand is necessary when prescribing by an electronic means.

In § 447.514(a)(1)(ii) we deleted “list the drug which has met” and “based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.”

In § 447.514(c)(2), we changed “30 percent” to “40 percent” per the outlier policy which will be implemented during the period of the final rule with comment period.

In § 447.514(c)(3), we clarified the regulation text by replacing “innovator single source” with “brand name.”

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 447.510 Requirements for Manufacturers

Section 447.510 states that a manufacturer must report, electronically, product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. In addition, customary prompt pay discounts and nominal prices must be reported quarterly. Detailed information

pertaining to the manufacturer's reporting requirements is located under §§ 447.510(a), (b), (c), (d), and (e).

The burden associated with these new requirements is the time and effort it would take for a drug manufacturer to gather product and pricing information and submit it to CMS in an electronic format. We estimate that these requirements would affect the approximately 550 drug manufacturers that currently participate in the Medicaid Drug Rebate Program. Our current reporting and recordkeeping hour burden for each manufacturer in the Medicaid Drug Rebate Program is 71 hours per quarter or 284 hours annually. We believe the new reporting requirements will require less than half of this time. Specifically, we believe it would take each manufacturer 31 hours per quarter or 124 hours annually to report additional new information to CMS. The total estimated burden on all drug manufacturers associated with the new requirements under § 447.510 is 68,200 annual hours. These new reporting requirements for drug manufacturers participating in the Medicaid Drug Rebate Program associated with the Medicaid Drug Program Monthly and Quarterly Reporting Form (CMS-367) are approved under OMB# 0938-0578. CMS will revise this collection to include changes in burden based upon this regulation.

Section 447.510(f) requires a manufacturer to retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The ten-year time frame applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised quarterly pricing data subsequently submitted to CMS. As stated under § 447.510(f)(2), there are certain instances when records must be maintained beyond the ten-year period.

While this requirement is subject to the PRA, the retention of quarterly data is not a new requirement and is

currently approved under OMB# 0938-0578. While this requirement will now also apply to monthly AMP data, we believe a similar set of data is now retained to support the quarterly retention requirement. It may require some additional record-keeping to retain the monthly, as well as the quarterly data, in the AMP system for manufacturers that do not retain this information there now. However, we believe that most manufacturers already have such monthly sales data (for example, data of sale information) in their system and transferring this to the system for calculating monthly AMP would not be a significant burden.

Section 447.520 FFP: Conditions Relating to Physician-Administered Drugs

Section 447.520 requires providers, effective January 1, 2007, to submit claims to the State for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

Assuming all States impose this requirement, the burden associated with this requirement is the time and effort it would take for a physician's office, hospital outpatient department or other entity (for example, non-profit facilities) to include the NDC on claims submitted to the State. We estimate this requirement would affect an excess of 20,000 physicians, hospitals with outpatient departments and other entities that would submit approximately 3,910,000 claims annually. We believe this would take approximately 15 seconds per claim. We estimated the cost based on the average annual wage and benefits paid for office and administrative support services in 2006 of \$21.14 per hour (www.bls.gov/news.release/pdf/ecec.pdf). The per claim cost would be under nine cents.

Many hospital outpatient departments will also need to modify their billing systems to capture the NDC on Medicaid claims (hospitals that receive discounted drugs and bill Medicaid at

the actual acquisition cost of the drug and hospitals that use a drug formulary system and bill at the hospital's purchasing cost are exempted). The American Hospital Association (AHA) in 2002 estimated that it would cost \$200,000 per hospital for changes needed to use NDC codes for billing. Inflating this figure by the Consumer Price Index (CPI) would make the current cost approximately \$230,000 for each of the 5,655 hospitals that participate in Medicaid for the total cost to be \$1.3 billion.

We are not adopting this estimate as we believe it to be high. This estimate was developed in 2002 to implement a stand alone NDC system from scratch. Since its development, FDA in 2004 issued a final rule requiring drug manufacturers to include Uniform Product Codes (bar codes) with NDC numbers on drug packages. In their final rule, FDA estimated a significant percent of hospitals would voluntarily start to implement bar-coding systems, in order to lower the number of medication errors and to realize other efficiency gains. Consistent with FDA's findings, some commenters noted that hospitals are planning to use bar codes on drugs in the future. When use of these codes is adopted, hospitals will be able to take the NDC from the bar code when billing Medicaid, minimizing the cost of implementing this provision.

Section 447.520(c) allows States requiring additional time to comply with the requirements of this section to apply for an extension. The burden associated with this requirement is the time and effort it would take for each State to apply for a one-time extension. We estimate that it would take five hours for each State to apply for the extension; however, we believe that only a few States will apply. Therefore, we believe this requirement to be exempt as specified at 5 CFR 1320.3(c)(4). We believe the total estimated annual burden for this rule is 84,492 hours.

OMB No.	Requirements	Number of respondents	Number of burden hours	Total annual burden
0938-0578	447.510	550 Drug Manufacturers	31 hours per quarter	68,200 hours.
None	447.520	20,000 Physicians	15 seconds per claim	16,292 hours.
None/Exempt	447.520(c)	Less than 10 States	NA	NA.
Total Annual Burden	84,492 hours.

We have submitted a copy of this final rule to the OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by the OMB.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of

Regulations Development, Attn: Melissa Musotto, [CMS-2238-FC] Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office

(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for “other drugs” set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or

(2) Providers’ usual and customary charges to the general public.

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like “brand necessary” is allowable.

(4) The agency may allow providers to keep the certification forms if the forms

will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in its most current edition of “Approved Drug Products with Therapeutic Equivalence Evaluations” (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.

(ii) At least two suppliers meet the criteria in paragraph (a)(1)(i) of this section.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid Program issuances.

(b) *Specific upper limits.* The agency’s payments for multiple source drugs identified and listed periodically by CMS in Medicaid Program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

(c) *Ensuring a drug is for sale nationally.* To assure that a drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS.

(2) Except as set forth in paragraph (c)(3) of this section, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 40 percent of the next highest AMP will be used to establish the FUL.

(3) When the FUL group includes only the brand name drug and the first new generic or authorized generic drug which has entered the market, the criteria in paragraph (c)(2) of this section will not apply.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency’s payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a) of this subpart, are in accordance with the upper limits specified in § 447.514(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in § 447.512 and 447.514 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the

Secretary as having the highest dollar value under the Medicaid Program using NDC numbers in order to secure rebates.

(b) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 27, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 29, 2007.

Michael O. Leavitt,

Secretary.

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