Biotechnology Industry Organization

May 21, 2015

The Honorable Howard A. Shelanski
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

BY ELECTRONIC SUBMISSION

Re: Information Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations [OMB No. 0915-0327—Revision]

Dear Administrator Shelanski:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments to the Office of Information and Regulatory Affairs (OIRA) in response to the Health Resources and Services Administration's (HRSA's) proposed Information Collection Notice entitled "Proposed Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Price Calculations"[1] (the "Notice"). BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

BIO represents an industry devoted to discovering new treatments and ensuring patient access to them. Accordingly, we support the 340B program as a way to improve access to therapies for needy patients. We believe that compliance with 340B program requirements by all parties—including manufacturers—is an important part of ensuring the sustainability of the 340B program. We also agree with HRSA that covered entities should have "confidence that the amounts being charged are in accordance with statutorily-defined ceiling prices."[2] We are concerned, however, that HRSA's proposed information collection request is both unnecessary and potentially unduly burdensome for manufacturers.

The following comments address our concerns with HRSA's burden estimate articulated in the Notice, which we believe is both difficult to verify, given the lack of detail provided in the Notice as to how the proposed information collection would be operationalized, and laughably small. We begin, however, with our concerns that this information collection is not necessary in the first instance. We also note, while that many of these concerns were articulated in BIO's letter to HRSA in response to the Agency's 60-day *Federal Register* Notice

[1] 80 Fed. Reg. 22,207 (Apr. 21, 2015).
[2] Id. at 22,208.

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issued last September,[3] it appears that HRSA has not responded to these comments, contrary to the "Information Collection Request Time Line" that appears on the Department of Health and Human Services' website.[4] Indeed, while the Paperwork Reduction Act (PRA) requires two separate notices, in part, to "consult with members of the public," it appears that the current Notice is a virtual a copy of the 60-day Notice HRSA issued last year.[5]

In light of these concerns, we urge OIRA either to disapprove this proposed collection of information or to instruct HRSA to make the substantive and material changes outlined in this letter pursuant to 5 C.F.R. § 1320.10(b).

I. The Proposed Information Collection Is Not Necessary for the Proper Performance of HRSA's Functions and Is Inconsistent with the PRA's Prohibition on Duplicative Reporting Obligations.

In the Notice, HRSA cites the new requirement that the Secretary develop a system to verify HRSA-calculated 340B ceiling prices based on data maintained by the Centers for Medicare & Medicaid Services (CMS) by comparing such ceiling prices to the quarterly data submitted by manufacturers to the Medicaid Drug Rebate Program (MDRP).[6] However, rather than rely on the data already reported to and maintained by CMS, the Notice proposes to require participating manufacturers to report all of the following quarterly pricing data to HRSA for each covered outpatient drug:

- Average Manufacturer Price (AMP);
- Unit Rebate Amount (URA);
- Package Sizes;
- National Drug Code (NDC);
- Period of Sale (year and quarter); and
- Manufacturer calculated ceiling price.

The draft reporting format that HRSA provided to OIRA with the request for approval to collect manufacturer ceiling price data would further require the provision of information as to:

- Unit Type;
- Case Pack;
- FDA Product Name;

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[3] This earlier HRSA notice was published in the Federal Register on September 30, 2014. See 79 Fed. Reg. 58,791 (Sept. 30, 2014).

[4] HHS.gov, Information Collection Request Timeline, http://www.hhs.gov/ocio/policy/collection/infocollectiontimeline.html (last visited May 18, 2015) (providing that, with respect to the 60-day Federal Register notice, "[i]f any comments are received, they need to be responded to and the response along with the comments are included with the ICR.").

[5] We obtained a copy of the clearance requests submitted to OIRA for review from HRSA's Information Collection Clearance Officer, as suggested in the Notice. However, notably absent from this submission were both the comments submitted in response to HRSA's earlier notice and HRSA's responses thereto. We later emailed HRSA requesting the comments received, to which HRSA replied that "the comments have been submitted to OMB for review, along with HRSA's response", but that "[w]e are unable to distribute this information externally." It is our position that this last statement is contrary to the applicable regulations, which require that the Agency shall provide, *for public inspection*, those materials provided to OMB—including a "summary of the public comments received [in response to the 60-day Notice], including actions taken by the agency in response to the comments." See 5 C.F.R. §§ 1320.14(a); 1320(a)(1)(iii)(F).

[6] 80 Fed. Reg. at 22,207-08.

- Labeler Name; and
- Wholesale Acquisition Cost (WAC).

As an initial matter, we note our concern that the data elements outlined in the Notice do not align with those included in the draft reporting format, thereby impeding the ability of stakeholders to submit informed comments as to the likely burden that this reporting obligation will impose.

We also are very concerned that this proposed information collection is neither necessary nor permitted. As an initial matter, we note that the statutory requirement to verify ceiling prices does not necessarily require that HRSA obtain all of its quarterly pricing data directly from manufacturers. Instead, the statute requires "the Secretary to verify the accuracy of ceiling prices calculated by manufacturers" by, among other things, "[c]omparing regularly the ceiling prices calculated by the Secretary with the quarterly reporting data that is reported by manufacturers to the Secretary."[7] In all three instances, the term "Secretary" refers to the Secretary of Health and Human Services (HHS)—the Department that includes both HRSA and CMS. This is relevant because manufacturers are already required to report AMP, package size, NDC, unit type, FDA product name, and period of sale on a quarterly basis to the Secretary (i.e., CMS) pursuant to the MDRP statute.[8] It is not likely that Congress intended for manufacturers to report this same pricing data twice to the same individual (the "Secretary").

In short, reading the 340B and Medicaid statutes together, it appears that Congress intended that HRSA would verify the accuracy of manufacturer-calculated ceiling prices, at least in part, by comparing the HRSA-calculated ceiling prices with the quarterly pricing data that is reported by manufacturers to CMS. Furthermore, we note that an alternative interpretation (i.e., that manufacturers must report AMP, package size, NDC, unit type, FDA product name, and period of sale to HHS twice) would be inconsistent with the federal Paperwork Reduction Act (PRA).

The PRA was enacted in order to reduce the total amount of paperwork burden the federal government imposes on private businesses and citizens, including through the coordination and integration of federal information resources management policies and practices.[9] To these ends, the PRA expressly requires the director of each federal agency to "certify . . . that each collection of information submitted to the Director [of the Office of Management and Budget [OMB]] for review . . . is not unnecessarily duplicative of information otherwise reasonably accessible to the agency."[10] This requirement does not appear to be

[7] PHS Act § 340B(d)(1)(B)(i)(II) (emphasis added).
[8] Social Security Act (SSA) § 1927(b)(3). See also CMS, Medicaid Drug Rebate Program Data, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html.
[9] Paperwork Reduction Act of 1980, Pub. L. No. 96-511, 94 Stat. 2812 (codified at 44 U.S.C. § 3501(1), (3)). The term "information resources management" is defined as "the process of managing information resources to accomplish agency missions and to improve agency performance, including through the reduction of information collection burdens on the public." 44 U.S.C. § 3502(7).
[10] 44 C.F.R. § 3506(c)(5). See also 5 C.F.R. § 1320.9(b) (same); 5 C.F.R. § 1320.5(d)(1)(ii) ("[t]o obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information: . . . [i]s not duplicative of information otherwise accessible to the agency . . . .")

met by aspects of HRSA's proposed information collection, particularly given that HRSA recognizes in the Notice that the Agency already has access to CMS's pricing data.[11]

On the other hand, we believe that HRSA could permissibly require manufacturers to report those data points that manufacturers do not report to CMS—namely the ceiling price and URA—without running afoul of Congressional intent or the PRA. Indeed, given that the manufacturer-calculated URA is considered the official URA for purposes of the MDRP, we strongly urge HRSA to rely on this URA—rather than the unofficial URA calculated by CMS—for purposes of verifying manufacturer-calculated ceiling prices under the Agency's statutory mandate.[12] Moreover, there are instances in which CMS's calculation of the URA can be different from manufacturers' (e.g., when manufacturers restate their reported AMP or Best Price for a specific time period), or when CMS does not calculate a URA at all,[13] further supporting the need for HRSA to rely on manufacturer-reported URAs for this purpose.

In light of the foregoing, believe that HRSA could permissibly rely on those pricing data reported to and maintained by CMS (to which HRSA already has access), and instead require that manufacturers report only manufacturer-calculated ceiling prices, URAs, and—in order to identify the drug and time period in question—NDCs and period of sale to HRSA.[14] We urge OIRA to disapprove the proposed collection of information unless modified accordingly. We also urge OIRA to ensure that any approved collection of information clearly articulates whether the obligation to report these data points (ceiling price, URA, NDC, and period of sale) would be optional or mandatory, as well as to outline its proposed processes for reconciling any differences in the ceiling price HRSA derives against that submitted by manufacturers, as neither is currently specified in the Notice.

II. The Estimated Burden is Well Below the Time It Would Take Manufacturers to Complete, Review, and Transmit the Requested Data, Let Alone Implement Systems Necessary to Comply with the New Reporting Obligation.

According to the Notice, HRSA has estimated that it would take each manufacturer 30 minutes per quarter to report all of the requested pricing information to HRSA.[15] We do not

[11] See 80 Fed. Reg. at 22,208 ("HRSA has already developed a system to prospectively calculate 340B ceiling prices from data obtained from [CMS] as well as OPA-identified commercial databases."). Indeed, the PPA requires manufacturers "to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement . . . ." Pharmaceutical Pricing Agreement § II(f).

[12] CMS uses the quarterly pricing data submitted by manufacturers (i.e., AMP and Best Price) to calculate an unofficial URA, which is submitted as a courtesy to the states. However, manufacturers are ultimately responsible for calculating the official URA. Notably, this official URA is transmitted to the states with the ROSI and payment, but not to CMS. CMS, Unit Rebate Calculation, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html. See also HHS-OIG, Medicaid Drug Rebate Dispute Resolution Could Be Improved, OEI-05-11-00580 (August 2014).

[13] See Medicaid Drug Rebate Data Guide for Labelers at 15 (Last Revised April 25, 2011) ("When labelers do not submit timely or complete pricing data, or their pricing data results in zero URAs, it is the labeler's responsibility to manually calculate the URA and send a rebate payment along with the ROSI.").

[14] We note that manufacturers will likely need to provide package size, period of sale, and, in some instances, the NDC together with ceiling price and URA data reports. As articulated in section III of this letter, we urge HRSA to use the same format used in the MDRP's DDR for reporting these data.

[15] 80 Fed. Reg. at 22,208.

believe that this is an accurate estimate of the proposed reporting burden. As HRSA outlines in the Notice, under the PRA, the term "burden" is defined as:[16]

> the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency, including: (i) Reviewing instructions; (ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information; (iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information; (iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information;(v) Adjusting the existing ways to comply with any previously applicable instructions and requirements;(vi) Training personnel to be able to respond to a collection of information; (vii) Searching data sources; (viii) Completing and reviewing the collection of information; and (ix) Transmitting, or otherwise disclosing the information.

We believe that 30 minutes would be sufficient to accomplish only one of these tasks: the actual transmission of the requested information. And even then, it is difficult to confirm the accuracy of that estimate without knowing the process HRSA proposes to require for such data submission (e.g., will it be through a web interface, like the Drug Data Reporting [DDR] system used by CMS for purposes of the MDRP? On a disk? Paper? Other?). In sum, we disagree that "[t]he burden imposed on manufacturers . . . is low because the information requested is readily available[,]"[17] given that: (1) it is not clear that the data submission requirements used by HRSA will be the same as those used by CMS; (2) manufacturers will need to take steps to prepare for the quarterly reporting obligation before it actually goes into effect; and (3) manufacturers will undoubtedly be required to spend time on the back-end resolving disputes with HRSA over disparate ceiling price calculations, particularly if there remain open questions with respect to certain, nuanced aspects of the ceiling price calculations—all factors that will result in manufacturers spending time that was not contemplated by the burden estimate outlined in the Notice. Each of these factors is addressed, in turn.

A. The Burden of Reporting the Requested Information Would Be Lower to the Extent HRSA Utilized the Same Format as, and Specified Timing After, the Quarterly Price Submission Process Used by CMS.

As noted previously, it is not clear that the reporting requirements imposed by HRSA will be the same as those used by CMS for purposes of the MDRP, including with respect to the reportable fields. For example, "Case Pack," which is a proposed field that manufacturers would be required to report to HRSA, is not a standard reportable field under the MDRP. As such, the addition of this data field would produce incremental burden for manufacturers to incorporate into their systems and the file format for HRSA. The same could be said for Wholesale Acquisition Cost (WAC). We have prepared a chart, provided as Appendix A, which compares the text files used in the DDR under the MDRP and HRSA's proposed text file for

[16] 5 C.F.R. § 1320.3(b)(1). See also 44 U.S.C. § 3502(2).
[17] 80 Fed. Reg. at 22,208.

purposes of 340B quarterly price reporting submissions. We also have attached the MDRP text files, as Appendix B, for your reference.[18]

To the extent that HRSA uses different data submission requirements, the burden on manufacturers would obviously be higher, given that manufacturers would need to re-format (or, potentially, manually re-enter) the requested data. For instance, in a survey of BIO members, two-thirds of respondents anticipated spending at least 10 hours responding to HRSA's request, assuming that the Agency did not employ the same reporting format as the MDRP's DDR; the same number anticipated spending fewer than 10 hours were HRSA to employ the same format. Accordingly, to the extent that OIRA permits HRSA to move forward with the proposed information collection, we urge OIRA to ensure that the Agency plans to use the same file format and utility as what already is being used by manufacturers to upload pricing data into the CMS's DDR system in order to minimize the burden of reporting the requested pricing data to HRSA.

On a related note, while the Notice does not address when the requested data would be due to HRSA, the burden on manufacturers would be much lower to the extent the data were due sometime after the quarterly submission deadline for pricing data to CMS, so that the new submission burden does not compound the already stressful quarterly submission process. We note that there are 60 days between when the quarterly numbers are calculated and when those numbers go into effect as the 340B price. To ensure that HRSA will have plenty of time to collate and verify these data, while staggering price reporting timelines sufficiently to mitigate the burden of any new reporting obligations on manufacturers, BIO therefore requests that the submission deadline be 45 days after the quarterly submission deadline to CMS. Any additional requirements related to the data reporting obligation should occur on this same schedule to further minimize the burden on manufacturers. We ask OIRA to take this into account in working with HRSA on this proposed collection of information.

B. Manufacturers Will Need to Take Preparatory Actions Prior to the First Quarterly Report That Were Not Factored into HRSA's Burden Estimate.

Before manufacturers are able to submit ceiling price data to HRSA during the first quarter, they will be required to take certain preparatory measures. For instance, it will be necessary for manufacturers to review HRSA's reporting instructions, create a reporting template, update their technology systems, run system and performance testing, adjust their compliance policies and procedures, train personnel, and take other steps to ensure compliance with the new reporting obligation. As noted previously, these are the types of activities that the PRA requires to be incorporated into an agency's burden estimate. Yet, it is clear that HRSA's 30-minute burden estimate does not take this time into account.

In addition, a recent update posted on HRSA's website requests that manufacturers "verify the accuracy and completeness of the information on file for each labeler code in the 340B Drug Pricing Program database."[19] To the extent any updates are necessary with respect to this information, HRSA further directs manufacturers to submit a "manufacturer

[18] We have attached two forms, as not all of the data fields proposed by HRSA are contained on the same DDR File layout.
[19] HRSA, Office of Pharmacy Affairs (OPA) Monthly Update: 340B Ceiling Price Calculation (May 2015).

change request form" to a designated email address. Each of these steps further adds to the preparatory burden.

Finally, HRSA's recent update also adds to the quarterly reporting burden by directing manufacturers to identify an authorizing official who is a "corporate officer or someone who would be otherwise authorized to legally bind the company to the terms of the Pharmaceutical Pricing Agreement (Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, etc.)." We note that this requirement will require the involvement, not only of these C-Suite officers, but of other employees, including technical experts who are familiar with the complex calculations that underlie this reporting obligation. Appropriate evaluation of the burden would require an assessment of the number and level of staff required to comply with the information collection. Similar to the data reporting format document, this additional request for manufacturers to update the database has not been reflected in the information collection request submitted to OIRA, even though it is central to assessing the overall burden of HRSA's information collection efforts.

C. Manufacturers Will Be Required to Spend Time Resolving Disputes with HRSA Over Disparate Ceiling Price Calculations that Was Not Contemplated in HRSA's Burden Estimate.

Another area that may increase the reporting burden on manufacturers relates to the potential for disputes with HRSA over ceiling prices calculations. While both manufacturers and HRSA will be calculating ceiling prices, HRSA has not addressed how it will reconcile any differences between the ceiling prices reported by manufacturers and those calculated by the Agency.[20] Nonetheless, we presume that manufacturers will spend time involved in this reconciliation process with the Agency.

Moreover, there are a significant number of questions as to how manufacturers should go about calculating ceiling prices that are not resolved in the Notice or elsewhere. For example, it is unclear how HRSA intends to address:

- Provisional pricing for newly launched products;
- Sub-ceiling pricing; and
- To the extent that HRSA plans to rely on the CMS-calculated URA,[21] instances in which there is a disparity between a manufacturer's URA and the URA calculated by CMS (e.g., products like line extensions that utilize alternative URAs, NDCs that failed CMS's variance test).

To the extent that these questions remain unresolved, manufacturers may not only spend unnecessary time in providing feedback, but there is an increased likelihood of disconnects between the data a manufacturer submits and HRSA's thoughts as to what the price should be. These disputes would undoubtedly increase the level of burden for both parties.

[20] HRSA's recent update addresses this, but only to note that manufacturers will receive a "system-generated e-mail notification to access the system and resolve the price discrepancies" and that "[i]f a discrepancy is not able to be resolved, HRSA will conduct additional inquiry and work with manufacturers to take corrective action, as necessary." Id. The Notice does not address, or even mention, this reconciliation process at all.

[21] As noted previously, BIO urges HRSA to rely on manufacturer-reported URAs, as opposed to URAs calculated by CMS, for purposes of the Agency's ceiling price verification activities.

Finally, while we appreciate that the Agency has provided some guidance as to the ceiling price calculation, we believe that some of this guidance also has the potential to create disputes. For instance, in HRSA's proposed file layout, the ceiling price would be calculated to six decimals, truncated to four, and then positions five and six would be padded with zeros. We suggest that the quarterly ceiling prices be reported in dollars and cents (i.e., 99999.99).[22] The requirement for additional decimal places, beyond two, will likely increase the burden due to any disputes that could arise with HRSA.

III. Conclusion

BIO thanks OIRA for this opportunity to comment on the Notice. As noted previously, we are concerned that the proposed information collection request is both unnecessary and unduly burdensome for manufacturers. We therefore urge HRSA to disapprove the proposed information collection request. To the extent that OIRA nonetheless permits HRSA to move forward with its proposal, we urge OIRA to instruct HRSA to take into account BIO's recommendations to lessen the burden imposed on manufacturers. Please contact me at (202) 449-6384 if you have any questions regarding our comments. Thank you for your attention to this important matter and for your consideration of BIO's views.

Respectfully submitted,

/s/

Erin Estey Hertzog, J.D., M.P.H.
Director, Health Law & Policy

[22] Wholesaler Acquisition Cost (WAC) is another field in HRSA's proposed file layout that should be reported in dollars and cents. HRSA also should clarify at what date WAC should be reported (i.e., beginning or end of quarter) in the file layout.

Appendix A: Comparison of Draft HRSA 340B Quarterly Pricing Data File to CMS MDRP DDR Data Text Files

HRSA 340B Quarterly Pricing Data Text File	Remarks	Compare to CMS MDRP DDR Data Text Files
Labeler Code	NDC#1	These data fields appear in the DDR Quarterly Pricing Data Text File
Product Code	NDC#2	
Package Size Code	NDC#3	
Period Covered	QYYYY	
Average Manufacturer Price	99999.999999	
Unit Rebate Amount	99999.999999	NEW
Package Size	9999999.999	This data field appears on the DDR Drug Product Data Text File as "Units Per Pkg Size"
Unit Type	e.g., CAP, TAB, ML	This data field appears on the DDR Drug Product Data Text File
Case Pack	9999999.999	NEW
340B Price		NEW
FDA Product Name		This data field appears on the DDR Drug Product Data Text File
Labeler Name		NEW
Wholesale Acquisition Cost	99999.999999	NEW

Appendix B:

CMS Record Specification DDR Data Text Files

CMS RECORD SPECIFICATION
DDR QUARTERLY PRICING DATA
TEXT FILE FOR TRANSFER TO CMS
Effective: January 1, 2008

Source: Drug Manufacturers
Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "Q"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size	2	11 – 12	NDC #3
Period Covered	5	13 – 17	QYYYY (Qtr/Yr)
Average Mfr Price	12	18 – 29	99999.999999
Best Price	12	30 – 41	99999.999999
Nominal Price	9	42 – 50	999999999
Customary Prompt Pay Disc.	9	51 – 59	999999999

QUARTERLY PRICING DATA FIELDS

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right-justified, zero-filled for 3-digit product codes.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right-justified, zero-filled for 1-digit package size codes.

Period Covered: Calendar quarter and year covered by data submission. Numeric 5-digit field, QYYYY.

Valid values for Q:
1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid values for YYYY:
4-digit valid calendar year.

Average Manufacturer's Price (AMP): The AMP per unit per product code for the period covered. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which is the same for all package sizes. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place ('.') and 6 decimal places; right-justified, zero-filled.

Best Price: Per the statute and rebate agreement, the lowest price available per product code, regardless of package size. Compute to 7 decimal places and round to 6 decimal places. Zero-fill for Non-Innovator Multiple Source drugs. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.

Nominal Price (NP): Sales that meet the statutory/regulatory definition of NP. Total dollar figure per 11-digit NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers; right-justified, 0-filled. If no sales for a package size, fill with all zeroes.

Customary Prompt Pay Discount (CPP): Total dollar figure per 11-digit NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers; right-justified, 0-filled. If no discount for a package size, fill with all zeroes.

CMS RECORD SPECIFICATION
DDR DRUG PRODUCT DATA
TEXT FILE FOR TRANFER TO CMS

Source: Drug Manufacturers

Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 – 1	Constant of "P"
Labeler Code	5	2 – 6	NDC #1
Product Code	4	7 – 10	NDC #2
Package Size Code	2	11 - 12	NDC #3
Drug Category	1	13 - 13	See Data Element Definitions
Unit Type	3	14 - 16	See Data Element Definitions
FDA Approval Date	8	17 - 24	MMDDYYYY
FDA Thera. Eq. Code	2	25 - 26	See Data Element Definitions
Market Date	8	27 - 34	MMDDYYYY
Termination Date	8	35 - 42	MMDDYYYY
DESI Indicator	1	43 - 43	See Data Element Definitions
Drug Type Indicator	1	44 - 44	See Data Element Definitions
Baseline AMP	12	45 - 56	99999.999999
Units Per Pkg Size	11	57 - 67	9999999.999
FDA Product Name	63	68 – 130	FDA Drug Listing Name
DRA Base AMP	12	131-142	99999.999999
Package Size Intro. Date	8	143-150	MMDDYYYY
Purchase Product Date	8	151-158	MMDDYYYY
Filler	17	159-175	spaces

DRUG PRODUCT DATA FIELDS

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right-justified, zero-filled for 3-digit product codes.

Package Size Code: Third segment of National Drug Code. ~~Alpha-~~numeric values, 2-digit field, right-justified, zero-filled for 1-digit package size codes.

Drug Category: Alpha-numeric values, 1 character.

Valid values:
- S = Single source
- I = Innovator multiple source
- N = Non-innovator multiple source

Unit Type: One of the 8 unit types by which the drug can be dispensed. Alpha-numeric values, 3-character field, left-justified.

Valid values:
- AHF = Injectable Anti-Hemophilic Factor
- CAP = Capsule
- SUP = Suppository
- GM = Gram
- ML = Milliliter
- TAB = Tablet
- TDP = Transdermal Patch
- EA = Each

FDA Approval Date: NDA or monograph approval date. If the drug was approved prior to the start of the Medicaid Drug Rebate Program (i.e., 10/1/1990), use 9/30/1990 as the FDA Approval Date. For covered outpatient drugs for which the FDA does not require approval, use 9/30/1990 or the actual date marketed if the drug was marketed after 9/30/1990. Numeric values, 8-digit field; format: MMDDYYYY

TEC: FDA-assigned Therapeutic Equivalence Codes. Alpha-numeric values, 2-character field.

Valid values:

AA	BC	BS
AB	BD	BT
AN	BE	BX
AO	BN	NR - Not rated
AP	BP	A1 thru A9 = AB value
AT	BR	

Market Date: For S and I drugs, the date the drug was first marketed by the original manufacturer (e.g., NDA holder). For N drugs, the date the drug was first marketed under the manufacturer's rebate agreement. If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in both the Medicaid Drug Rebate (MDR) system and the Drug Data Reporting for Medicaid (DDR) system since dates earlier than the start of the Drug Rebate Program have no bearing on this aspect of the program. Numeric values, 8-digit field, format: MMDDYYYY

Termination Date: The date a drug is withdrawn from market or the drug's last lot expiration date. Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY

DESI Indicator: Drug Efficacy Study Implementation code. Numeric value, 1 digit.

Valid values:
- 2 = Safe and effective or DESI Drug Pending FDA Review
- 3 = Drug under review (no NOOH issued)
- 4 = LTE/IRS drug for some indications
- 5 = LTE/IRS drug for all indications
- 6 = LTE/IRS drug withdrawn from market

Drug Type Indicator: Identifies a drug as prescription (Rx) or over-the-counter (OTC). Numeric values, 1-digit field.

Valid values:
- 1 = Rx
- 2 = OTC

OBRA '90 Baseline AMP: The AMP per unit for the period that establishes the OBRA '90 Baseline AMP for innovator drugs. There will be one weighted baseline AMP for the product, which will be the same for all package sizes. Compute to 7 decimal places and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled for innovator drugs (i.e, S or I drugs) with a Market Date of 10/1/1993 or greater and for all non-innovator drugs.

Units Per Package Size: Total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values, 11-digit field: 7 whole numbers, the decimal ('.') and 3 decimal places; right-justified, zero-filled.

FDA Drug Listing Name: Drug name as it appears on FDA listing form. Alpha-numeric values, 63 characters, left-justified.

DRA Baseline AMP: For active innovator drugs with a Market Date less than July 1, 2007, the OBRA '90 or OBRA '93 Baseline AMP revised, at labeler option, in accordance with relevant regulations and program guidance. There will be one weighted DRA Baseline AMP for the product, which will be the same for all package sizes. Per CMS-2238-FC, labelers will have four quarters (i.e., January 2, 2008-October 30, 2008) to report this optional field. Numeric values, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places, right-justified, zero-

filled. Compute to 7 decimal places and round to 6 decimal places. PLEASE NOTE: This field is now closed as the deadline for reporting (i.e, 10/30/2008) has passed; therefore, no additional DRA Baseline AMP submissions will be allowed.

Package Size Introduction Date: The date the package size is first available on the market. If the product was purchased from another company, the Package Size Introduction Date should equal the date the package size is first available on the market under the labeler code of the company currently holding legal title to the NDC. Numeric values, 8-digit field, format: MMDDYYYY

Purchased Product Date: The date on which the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc…). Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY

Filler: Spaces