

### **Comments Regarding the Identification of 5i Drugs (§447.507)**

We received the following PRA-related comments regarding the identification of 5i drugs. A summary of the comments along with our response follow.

Comment: Several commenters noted that our estimates associated with a drug manufacturer's burden to identify 5i drugs and determine whether such drugs are not generally dispensed through retail community pharmacies were low. In particular, commenters noted that it would take 40 hours per month to perform a manual analysis regarding which drugs are subject to the 5i AMP methodology, which they believe is equivalent approximately to one-fourth of work time of a full-time employee. Another commenter noted that it would cost approximately \$150,000 per year for drug manufacturers to identify 5i drugs including those not generally dispensed through retail community pharmacies, which is the cost for one additional full-time employee.

Response: In the proposed rule, we estimated that it would take 20 hours per response with 16 responses per year for each drug manufacturer to identify which 5i drugs are not generally dispensed through a retail community pharmacy. Because we received comments noting that our estimate was low, and we received a specific comment estimating that it would take 40 hours per drug manufacturer to perform the analysis for this requirement, we decided to increase our burden estimate from 20 to 30 hours monthly per response for drug manufacturers to identify which 5i drugs are not generally dispensed through a retail community pharmacy and an additional 1.0 hour per month for drug manufacturers to report this information to CMS. Given the comments received and the need to increase our estimate from 20 hours, we believe this revised estimate is sufficient and appropriate as it is halfway between our original estimate and the specific comment that we received. The requirement and burden estimate for performing this analysis will be submitted to OMB under control number 0938-0578 (CMS-367).

### **Comments Regarding Medicaid Drug Rebates (§447.509)**

We received the following PRA-related comments regarding Medicaid drug rebates. A summary of the comments along with our response follow.

Comment: A few commenters from organizations representing states indicated that the cost associated with the collection of Medicaid MCO rebates on states appears to be underestimated. One of the commenters stated that the cost to states for collecting Medicaid MCO rebates could be more than \$400,000 annually, but will vary from state to state. Another commenter stated that CMS's estimate of costs associated with the collection of Medicaid MCO rebates was underestimated by approximately \$100,000 annually.

Response: As discussed in preamble section II.G.3., we are not finalizing the Medicaid MCO reporting requirements that were proposed under §447.509(b)(3). Instead, we address the requirements for states with regard to the data they report to drug manufacturers, including the data pertaining to Medicaid MCO utilization, under §447.511. The ICRs and burden associated with the state invoice and state utilization data reporting associated with Medicaid MCO rebates within the MDR program for the current state Medicaid programs is approved by OMB under control number 0938-0582 (CMS-368 and CMS-R-144).

### **Comments Regarding Requirements for Manufacturers (§447.510)**

We received the following PRA-related comments regarding requirements for drug manufacturers. A summary of the comments along with our response follow.

Comment: Several commenters expressed concern that the estimates we provided in the proposed rule are not an accurate reflection of the costs that drug manufacturers will incur to develop and test updated systems in order to implement several requirements in the proposed

rule, including the determination of AMP, 5i drugs, best price, and general cost of data analysis. A few of those commenters noted in particular that the estimate does not reflect the costs a drug manufacturer would incur in implementing the build-up model for AMP versus the presumed inclusion model.

Response: While we appreciate the comments that noted our estimates are low, we are unable to revise them in the absence of specific data or information. Further, because we are not finalizing the buildup methodology requirement and have retained the longstanding presumed inclusion methodology for drug manufacturers to calculate AMP, we do not need to include costs associated with the buildup model in this final rule.

Comment: Several commenters shared their concern regarding requirements associated with Affordable Care Act changes and shared their thoughts on burden estimates and costs associated with the drug manufacturer requirements to pay rebates in accordance with the changes made by Affordable Care Act including the costs of determining which sales are in and out of AMP, drafting policy decisions and assumptions, systems changes, changing to a buildup approach, and training costs. Specifically, a commenter noted that it would need to hire a team of 10 full-time contracted Information Technology (IT) professionals at a rate higher than the \$60/hr that CMS estimated, and that the drug manufacturer would incur the following expenses to implement all of CMS's proposals: \$2.65 million for upfront costs; spend 3 months and cost \$400,000 for finalizing new AMP and best price calculation methodologies; take 12 months and cost \$1 million for updating wholesaler data to implement the new rule, not including the IT-contractor cost and additional cost to purchase data; take 9 months and cost \$500,000 to modify price report systems to include U.S. territories, not including programming cost.

Another commenter estimated that it would take 4 months and cost \$250,000 to analyze how 25,000 existing customers should be categorized under the new AMP inclusions and

exclusions; take 3 months and cost \$500,000 for drafting new assumptions, policies, documents, and training employees and \$4.2 million for reprogramming cost.

Response: As discussed previously in the Determination of AMP section of this rule (section II.C.), we have decided not to require that drug manufacturers adopt the buildup approach when calculating AMP in which drug manufacturers were to report AMP based solely upon their actual sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies. Instead, we believe it is reasonable that drug manufacturers continue to presume, in the absence of guidance and adequate documentation to the contrary, that prices paid to drug manufacturers by wholesalers are for drugs distributed to retail community pharmacies, provided those assumptions are consistent with the requirements of section 1927 of the Act and federal regulations. Therefore, a drug manufacturer's time and effort as noted in the comments pertaining to the buildup model will not be considered as an impact of this final rule. We believe this will greatly alleviate the need for the drug manufacturer to make system changes necessary to process, validate, and reconcile data concerning the actual distribution; hence reducing the costs and burden on drug manufacturers to pay rebates associated with the changes in the Affordable Care Act and adopted as part of this final rule.

However, we have revised our estimates pertaining to the implementation of the revised definitions of AMP and best price under the existing presumed inclusion approach. Specifically, we have revised our estimates to reflect that reconfiguring the manufacturers' pricing systems to implement the AMP and best price definitions will require 1,200 hours per drug manufacturer, for a one-time total of 732,000 hours with a one-time total cost of \$67,175,884 for 610 participating drug manufacturers. In addition to the one-time burden of reconfiguring pricing systems, we estimate a one-time start-up cost of \$384,704 per drug manufacturer, with 610 participating drug manufacturers, totaling \$234,669,440. Once the pricing systems have been

reconfigured, there should be no additional burden in time or effort other than that which already exists.

We will work with drug manufacturers regarding the collection of data they need from the territories to pay their rebates. We have accounted for the administrative and financial burden associated with the changes to the definitions of AMP and best price in the burden estimates in this section, and we considered the changes necessary to collect data on sales to territories to be included in these estimates. As previously noted in the Definition section of this final rule (section II.B.20.), the inclusion of the territories in the definitions of state and United States is effective 1 year after the effective date of the final rule. Therefore, the application of the MDR program to the territories is also effective 1 year after the effective date of this final rule; which we believe will enable the drug manufacturers to make the necessary changes in their systems.

#### **Comments Regarding Requirements for States (§447.511, §447.512, and §447.518)**

We received the following PRA-related comments regarding requirements for states, including comments pertaining to the costs associated with the territories coming into compliance with the requirements of the MDR program. A summary of the comments along with our response follow.

Comment: One commenter stated that CMS did not consider the costs to the territories of implementing a rebate system for territories and stated that it estimated these costs at a minimum of \$500,000 annually. Another commenter noted that a specific territory would need to take several actions to ensure compliance with the requirements of the final rule including upgrade its current computer systems and estimated the cost at \$500,000 to \$900,000 to hire a contractor to perform the upgrades.

Response: We appreciate this comment. As noted in the proposed rule, we did not have any estimates of the costs that the territories would incur by participating in the MDR program. Since we only received one comment with an estimate of cost for the territories to implement a rebate system, we have based our estimate in this final rule on that comment, as well as the information we have obtained regarding the salaries for certain occupations that would be involved in this process (see Table 1: Hourly Wage Estimates). We believe it is reasonable to expect that the territories will have to hire a contractor that specializes in the MDR program to develop the system to collect rebates from drug manufacturers. Furthermore, based on the estimates that we have included above (see section III.B.4. of this final rule) for drug manufacturers to reconfigure their pricing systems to correctly calculate AMP and best price, we believe that the estimate provided by the commenter is consistent with what it would cost for the territories to implement the rebate system by utilizing a contract with expertise in the MDR program. Therefore, we are estimating that each territory that chooses to participate in the program will incur a minimum of a one-time cost of \$500,000 to participate in the rebate program. We are also estimating that the on-going operational costs will be \$500,000 annually for the territories that participate in the program. Because the rebate requirements pertaining to the territories will not become effective until 1 year after the effective date of this final rule, we will submit these costs in a future PRA package and have not included these costs in Table 2.

Comment: Several commenters stated that CMS did not take into account the costs associated with annual AAC surveys and periodic dispensing fee surveys. The commenters report that these costs could be in the range of \$50,000 - \$100,000 per survey.

Response: Although we are requiring in §447.518 that states must provide adequate data such as a state or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the

reimbursement methodology, we are not requiring states, on their own, to perform acquisition cost surveys. We have provided states with two reimbursement benchmarks that they can use in determining AAC; AMPs, which are reported and certified by drug manufacturers, and NADAC, which is based on a national survey. Therefore, we have not included time and cost burdens for individual state ingredient cost surveys and dispensing fee surveys in this final rule. During the SPA process, the state must demonstrate how such disclosure of the AMP-based prices are consistent with the confidentiality requirements set forth by the statute and other applicable federal regulations and statutory requirements, including the requirement in section 1902(a)(30) (A) of the Act that payments be consistent with efficiency, economy and quality of care and sufficient to assure access.

We recognize that there will be some additional burden to the states to implement the new AAC and professional dispensing fee requirements, as well as the new reimbursement requirements for the FULs and other federal programs, such as 340B, IHS, and I/T/U. This burden may include the time and cost for administrative processes and requirements such as legislative and regulatory action, operational changes, and the submission of a SPA for formal review; therefore, we are revising the state estimate for these burdens to include an additional 300 hours per state.