



May 18, 2010

Cynthia Mann  
Director  
Center for Medicaid, CHIP and Survey & Certification  
7500 Security Blvd.  
Baltimore, MD 21244

Re: Rebates

Dear Ms. Mann:

I am writing to you on behalf of the National Association of State Medicaid Directors (hereinafter “NASMD”) as our member states have a number of concerns about the guidance regarding Medicaid prescription drug rebates. Specifically, I would like to draw your attention to the following concern. The State Medicaid Director’s letter of April 22, 2010, regarding Medicaid prescription drug rebates under the Affordable Care Act (SMDL #10-006) provides that for brand name drugs now subject to a 23.1% or 17.1% minimum rebate, CMS plans to offset an amount equal to the non-Federal share of the increase in the minimum rebate, “regardless of whether States received a rebate amount based on the difference between AMP and best price.” NASMD believes that any such offset from a rebate based on the difference between AMP and best price would be a clear violation of the Affordable Care Act.

Under section 1927(c)(1)(A)(ii) of the Social Security Act, both before and after the Affordable Care Act, federally required drug rebates are based on the greater of:

1. The difference between AMP and best price, or
2. The applicable minimum rebate percentage of AMP.

Under section 1927(c)(2)(A), inflation-based increases may apply to either base – the difference between AMP and best price, or the applicable minimum. The only piece of this formula changed by the Affordable Care Act is the minimum rebate percentages. Therefore, if the difference between AMP and best price for a particular drug exceeds both the old and the new minimum, the rebate for that drug will be unaffected by the Affordable Care Act. In such cases, both the old and the new rebates are based on the difference between AMP and best price, not on the minimums. In other words, the rebate applicable after the Affordable Care Act is unaffected by the change in the minimum and unchanged from the rebate paid prior to the Affordable Care Act.

After providing for the increases in the minimum rebates for brand-name drugs, in section 2501(a)(1), the Patient Protection and Affordable Care Act goes on to provide as follows in section 2501(a)(2):

***Recapture of total savings due to increase.***--Section 1927(b)(1) of such Act (42 U.S.C. 1396r-8(b)(1)) is amended by adding at the end the following new subparagraph:

(C) Special rule for increased minimum rebate percentage.—

(i) In general.--In addition to the amounts applied as a reduction under subparagraph (B), ... the Secretary shall reduce payments to a State ... in an amount equal to the product of—

(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

(II) ***the amounts received by the State*** under such subparagraph ***that are attributable*** (as estimated by the Secretary based on utilization and other data) ***to the increase in the minimum rebate percentage*** effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act

....

(Emphasis added.) The application of this provision to a rebate that is unaffected by the increase in the minimum rebate violates both the letter and the apparent intent thereof. By its terms, this provision applies only to “amounts received by the State ... that are attributable ... to the increase in the minimum rebate percentage.” There is no such amount if a rebate is unaffected by the change in the applicable minimum. Further, the application of this provision to an unchanged rebate is not a federal “recapture” of any new “savings due to increase.” Rather, it is a shift of existing savings, due to the current rebate formula, from the states to the federal government. To illustrate this point, we cite the example given by Larry Reed on the Managed Care TAG call May 5, 2010. Staff from various states asked Mr. Reed how they could begin to estimate the effect of the recaptured rebates. In explaining that all rebates would not be affected by the Affordable Care Act, Mr. Reed gave these two examples:

(1) Rebate for Drug A is based on 15.1% of AMP minimum rebate, plus 14.9% CPI rebate for a total of 30% of AMP. Under PPACA, this drug’s rebate will now be 23.1% as the minimum base rebate plus 14.9% CPI, for a total of 38% of AMP.

(2) Rebate for Drug B is based on Best Price and equates to 23.1% of AMP, plus 6.9% CPI rebate for a total of 30% of AMP. Under PPACA, this drug’s rebate will not change.

Despite the fact that the rebate for drug B is unchanged, Mr. Reed indicated that the federal rebate offset or recapture would apply to that portion of the unchanged rebate equal to 8% of AMP. As explained above, we believe that violates the Affordable Care Act. NASMD respectfully requests that CMS reconsider its position in regard to the application of the federal rebate offset or recapture to rebates that are unaffected by the increase in the minimum rebate.

CMS also stated on the May 5, 2010, Managed Care TAG conference call that States would be responsible for calculating the recapture amount based on AMP data disseminated by CMS. Initially, States had several concerns on this option, including information that will not be available to the States, such as Best Price and CPI data and identification of drugs falling under the line extension, clotting factor drugs and drugs for pediatric use rebate carve-out. Additional factors that will cause considerable administrative challenges for a State-calculated recapture amount and will potentially result in inaccurate and inconsistent outcomes include retroactive adjustments to the AMP reported by manufacturers (hence Prior Period Adjustments to the Unit Rebate Amount [URA]), and various methods of calculations among States, rebate Contractors, claims processors, manufacturers, and CMS. Lastly, fundamental legal questions arise when looking at how the Affordable Care Act outlines that the “***the amounts received by the State... (as estimated by the Secretary based on utilization and other data)***” (emphasis added). However, on a subsequent May 13, 2010, Pharmacy TAG call, there was a detailed discussion related to the possibility of two options:

- 1) The recapture amount being calculated by CMS: In this option, CMS stated they would be prohibited from sharing the AMP data with the States for recapture amount validation purposes, and the recapture amount would be immediately applied prior to States invoicing manufacturers.
  
- 2) The recapture amount being calculated by the States: In this option, CMS stated the AMP data would be shared with States for the sole purpose of recapture amount calculation and validation.



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There was a discussion that the released AMP data would only be available for rebate recapture amount, and not any other purpose (ie reimbursement). The recapture amount would be applied after the States invoiced manufacturers and received payments for those invoices.

Due to the vast issues related to each option, coupled by the fact that not all States have been in attendance for all CMS conference calls, NASMD respectfully requests that CMS develops written guidance for each option, to include details on how CPI penalties, Best Price, line extensions, clotting factor drugs, pediatric drugs, retroactive AMP changes, NDC-level reporting, ongoing and prospective litigation regarding the release of AMP data, and other factors can affect the calculation *in each scenario*. In addition, specific calculation instructions on the calculation are requested; in Option 1) it would benefit States to gain a detailed understanding of how CMS anticipates the calculation to be applied, and in Option 2) States need the detailed instructions to perform the calculation so that the States' procedures would not be subject to repeated questions from auditors and increased demand on already limited staffing resources. Consistent with our request above regarding application of the federal rebate recapture to rebates that are unaffected by the increase in the minimum rebate, we request that both options allow for the exclusion of such rebates from the calculation of the recapture amount. We also request that CMS reconsider its stated position that CMS's calculation of the recapture amount would require that the amount be applied immediately, as recovery of an overpayment, prior to invoicing of manufacturers for rebates. The Affordable Care Act provides that the recapture amount will be "deemed an overpayment" only as a "manner of payment reduction." (New section 1927(b)(1)(C)(ii).) And the recapture amount is defined as a portion of "the amounts received by the State" as rebates from manufacturers. Thus, there can be no recapture amount to be collected as an overpayment until a rebate is "received by the State." With this additional guidance, the states will be able to make an informed decision and a collective recommendation to CMS (through NASMD) regarding responsibility for calculation of recapture amounts.

Lastly, given the retroactive nature of this provision, it is vitally important for states to be able to calculate what the impact is on their budgets. Currently, as your pharmacy staff has stated, states are unable to make these calculations as they do not have the necessary information to do these calculations. Therefore we are requesting that you assist the states with this information so that the appropriate calculations for both FY 2010 and FY 2011 can be made.

In addition to the concerns outlined above there are a number of additional questions the state Medicaid programs have with regard to the information that has been provided thus far and we are attaching them to this letter. Some of these concerns include questions regarding line extensions, managed care organizations, & pediatric indications, as well as requests for more information as to the timeline for your future guidance on this topic.



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Thank you very much for your time and attention to these matters. States have a number of overarching concerns and questions that require additional written guidance. States would greatly appreciate receiving this guidance as soon as possible. We look forward to our continued work and discussions with you to ensure that guidance is disseminated to all the states in a timely manner.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann Clemency Kohler".

Ann Clemency Kohler  
NASMD Director

Cc: Kathleen Nolan, NGA  
Brian Webb, NAIC  
Alan Weil, NASHP  
Paul Dioguardi, HHS  
Jennifer Ryan, CMS  
Matt Salo, NGA