DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26 12
Baltimore, Maryland 21244-1850

Center for Medicaid, CHIP and Survey & Certification

SMDL#10-019
ACA# 9

September 28, 2010

Re: Medicaid Prescription Drugs

Dear State Medicaid Director:

This letter is one of a series intended to provide guidance on the implementation of the Patient Protection and Affordable Care Act (P.L. 111-148), enacted on March 23, 2010, as revised by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152), enacted on March 30, 2010, together known as the Affordable Care Act.

Specifically, this letter revises the previous instructions concerning the Federal offset of Medicaid prescription drug rebates, and further specifies the process we will use for the estimation and collection of these offsets. It also provides information on rebates for Medicaid managed care organization (MCO) drugs, MCO formularies, and the treatment of MCO physician-administered drugs. Finally, this guidance addresses manufacturer reporting requirements, the treatment of discounts under the Medicare Coverage Gap Discount Program for purposes of the determination of best price (BP), and the changes to the excluded drug provisions in Medicaid.

Revised Policy on Federal Offset of Rebates

Section 2501 of the Affordable Care Act increased the amount of rebates that drug manufacturers are required to pay under the Medicaid drug rebate program, with different formulas for single source and innovator multiple source drugs (brand name drugs), noninnovator multiple source drugs (generic drugs), and drugs that are line extensions of a single source drug or an innovator multiple source drug, effective January 1, 2010. The Affordable Care Act also required that amounts "attributable" to these increased rebates be remitted to the Federal government.

In the April 22, 2010 State Medicaid Director (SMD) letter, #10-006, CMS indicated that we were planning to offset the non-Federal share of the entire difference between the minimum rebate percentages in effect on December 31, 2009, and the new minimum rebate percentages in effect under the Affordable Care Act, regardless of whether States received a rebate amount based on the difference between the average manufacturer price (AMP) and best price (BP). For a drug that is a line extension of a brand name drug that is an oral solid dosage form, we planned to offset the entire non-Federal share of the increase in the minimum, as well as the additional rebate for those drugs. However, after further consideration of the offset provisions in section

2501 of the Affordable Care Act, we have decided to reconsider our instructions regarding the calculation of the offset provisions to reflect the lesser of the difference between the increased minimum rebate percentage and the AMP minus BP. We plan to offset the amount equal to the increased amount of rebates resulting from the Affordable Care Act.

In light of this reconsideration, we plan to calculate the offset as described below.

Brand name drugs other than blood clotting factors and drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications[1] are subject to a minimum rebate percentage of 23.1 percent of AMP:

- If the difference between AMP and BP is less than or equal to 15.1 percent of AMP, then we plan to offset the full 8 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

- If the difference between AMP and BP is greater than 15.1 percent of AMP, but less than 23.1 percent of AMP, then we plan to offset the difference between 23.1 percent of AMP and AMP minus BP.

- If the difference between AMP and BP is greater than or equal to 23.1 percent of AMP, then we do not plan to take any offset amount.

Brand name drugs that are blood clotting factors and drugs approved by the FDA exclusively for pediatric indications are subject to a minimum rebate percentage of 17.1 percent of AMP:

- If the difference between AMP and BP is less than or equal to 15.1 percent of AMP, then we plan to offset the full 2 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

- If the difference between AMP and BP is greater than 15.1 percent of AMP, but less than 17.1 percent of AMP, then we plan to offset the difference between 17.1 percent of AMP and AMP minus BP.

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[1] Guidance and list of blood clotting factors and drugs approved by the FDA exclusively for pediatric indications are posted on the CMS website at http://www.cms.gov/Reimbursement/08_MedicaidPrescriptionDrugsundertheAffordableCareAct.asp.

- If the difference between AMP and BP is greater than or equal to 17.1 percent of AMP, then we do not plan to take any offset amount.

For a drug that is a line extension of a brand name drug that is an oral solid dosage form, we plan to apply the same offset calculation as described above to the basic rebate. Further, we plan to offset only the difference in the additional rebate of the reformulated drug based on the calculation methodology of the additional rebate for the drug preceding the requirements of the Affordable Care Act and the calculation of rebates for the reformulated drug, if greater, in accordance with the Affordable Care Act. If there is no difference in the additional rebate amount in accordance with the Affordable Care Act, then we do not plan to take any offset amount.

We have not reconsidered our guidance with respect to generic drugs, given that rebates are not calculated based on best price. Thus, we plan to continue to offset an amount equal to two percent of the AMP (the difference between 13 percent of AMP and 11 percent of AMP).

As indicated in our April 22, 2010 guidance, we do not plan to offset the non-Federal share of any supplemental rebates States may receive above the increased Federal rebate percentages.

Offset Rebate Methodology

When determining the best approach to calculating the offset amount, we considered States,' as well as CMS's data and systems capabilities. Some States suggested that it would be more efficient for CMS to perform this offset calculation in a manner similar to the calculation of the unit rebate amount (URA). States also suggested that CMS calculate a second URA identifying the amount of offset to be returned to the Federal Government.

After considering these suggestions and to avoid the potential burden on States, we have decided that it would be more efficient for CMS to determine the offset amount. Accordingly, we plan to calculate a unit rebate offset amount (UROA) that will identify the offset amount per unit of a drug at the 9-digit national drug code (NDC) level on a quarterly basis for States. States will then be able to apply the UROA to the number of units of each drug for which they receive payment from a manufacturer to determine the Quarterly Rebate Offset amount (QROA) for each drug of all manufacturers to determine the total QROA. This amount will be offset and reported on the Quarterly Expenditure reports.

We are in the process of implementing the systems changes necessary to include the UROA with the quarterly rebate data submissions to the States. We believe States will also need more time to modify their respective systems to accept this new UROA data element. Therefore, we are developing an interim process to calculate an estimated quarterly rebate offset amount (EQROA) that will be used to approximate this offset until our UROA systems changes are finalized. We plan to apply the UROA for the basic rebate to an estimation of units for which the State has made payment under the Medicaid State plan and reduce that estimate by the amount of rebates we expect the State would have received in the quarter. We further plan to make this estimate available to the State and record it on behalf of each State on the form CMS-64 as an offset. The

EQROA amount will be reconciled with the total QROA when CMS provides States with the UROAs. Attached to this letter is a detailed description of the methodology we plan to use for the EQROA interim process for estimating the total offset.

Because we do not currently have the capability to systematically identify reformulated drugs, the additional rebate for those drugs is not included for the purpose of this calculation, and no offset will be taken from the States at this point. Once these drugs are identified, we will include them in the EQROA or UROA process, and will make necessary retroactive adjustments.

Rebates for Medicaid Managed Care Organization (MCO) Drugs – MCO Formularies and MCO Physician-Administered Drugs

We have received questions on whether the legislation also requires Medicaid MCOs to revise their current formularies. As noted in the April 22, 2010 SMD letter, the new legislation requires manufacturers to provide rebates for drugs dispensed to individuals enrolled in a Medicaid MCO. The changes made by section 2501(c) of the Affordable Care Act do not specifically revise the requirements concerning the provision of drugs by an MCO to its members, but they do provide that utilization information concerning covered outpatient drugs dispensed by an MCO to its Medicaid enrollees are to be reported to the State. This reporting will enable the State to include MCO utilization data with its fee-for-service utilization data for covered outpatient drugs, so that the manufacturers can pay rebates on these drugs. Accordingly, we do not plan to require that an MCO modify its formulary provisions in light of this provision of the Affordable Care Act. MCOs may continue to have some flexibility in maintaining formularies of drugs regardless of whether the manufacturers of those drugs participate in the drug rebate program. State Medicaid agencies may continue to establish requirements regarding MCOs' formularies.

We also received questions related to State responsibility for collecting rebates for physician-administered drugs provided in an MCO and MCO responsibility for collecting and reporting rebate data on such drugs (e.g., NDCs and number of units of each covered outpatient drug dispensed) for transmission to the State. In light of the requirements of section 1927(a)(7) regarding the collection of information for physician administered drugs, MCOs are responsible for submitting utilization data for these covered outpatient drugs to the State.

Exemptions for Discounts under the Medicare Coverage Gap Discount Program from Best Price

In accordance with section 1927(c)(1)(C)(i)(VI) of the Social Security Act, as revised by section 3301(d) of the Affordable Care Act, effective July 1, 2010, discounts provided by manufacturers under the Medicare Coverage Gap Discount Program under section 1860D-14A of the Act are also exempt from a manufacturer's BP calculation.

Reporting Units

Beginning with October 2010, section 2503(b) of the Affordable Care Act requires manufacturers to report the total number of units that are used to calculate the monthly AMP for each covered outpatient drug no later than 30 days after the last day of the month. We plan to require manufacturers to report these units by the same unit type used to calculate the AMP and we plan to use these units to calculate the weighted AMP-based FULs prices. We plan to have the data field necessary for manufacturers to report this data and will provide instructions to manufacturers regarding the reporting of units to facilitate timely reporting in advance of the deadline.

Excluded Drug Provision Changes

Section 2502 of the Affordable Care Act requires that over the counter (OTC) and prescription smoking cessation drugs, barbiturates, and benzodiazepines be removed from the list of drugs that States may exclude from coverage, effective January 1, 2014. States will generally be required to cover these products to the extent that States provide coverage of prescribed drugs. Please note that because Medicare Part D does not require the coverage of OTC smoking cessation drugs, States are responsible for coverage of such drugs for Medicaid dual-eligible individuals, provided that the State provides a prescription drug benefit under its State plan for such Medicaid beneficiaries.

We intend to issue further guidance and regulations as necessary to ensure the proper and timely implementation of these and related provisions of the Affordable Care Act. We look forward to our continuing work together to implement this legislation. Questions regarding Medicaid drug provisions can be submitted through the drug policy resource mailbox at RxDrugPolicy@cms.hhs.gov or may be directed to Larry Reed, Director, Division of Pharmacy, Disabled and Elderly Health Programs Group at (410) 786-3325.

Sincerely,

/s/

Cindy Mann
Director

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
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Enclosure

METHODOLOGY FOR CALCULATING THE ESTIMATED QUARTERLY REBATE OFFSET AMOUNT

Effective January 1, 2010, the Affordable Care Act increased the minimum rebate amounts that drug manufacturers are required to pay under the Medicaid drug rebate program, with different formulas for single source and innovator multiple source drugs (brand name drugs) and noninnovator multiple source drugs (generic drugs). The Affordable Care Act also required that amounts "attributable" to these increased rebates be returned to the Federal Government.

We have provided a detailed description below of CMS' methodology for the estimated quarterly rebate offset amount (EQROA) interim process for estimating the total offset amount that will be remitted to the Federal Government for this provision. The EQROA amount will be reconciled with the total quarterly rebate offset amount (QROA) when CMS provides States with the unit rebate offset amounts (UROAs).

Using the most complete available data, we plan to calculate the EQROA using the following methodology. We note the limitations in using the data for this calculation in the data limitations section at the end of this paper.

ACRONYMS AND ASSOCIATED FORMULA

UROA = Unit Rebate Offset Amount = Quarterly AMP x Offset Rebate Percentage per NDC
QROA = Quarterly Rebate Offset Amount = UROA x Average Total Units per NDC
Total QROA = Sum of the QROA of all NDCs
EQROA = Estimated Quarterly Rebate Offset Amount = Total QROA x Discount Factor Percentage Specified Below

DATA SOURCES

- Quarterly AMP Data, Begins with 1Q2010 (1st quarter of calendar year 2010)
- 3Q2008 – 2Q2009 Total Number of Units Reimbursed by States Obtained from the Medicaid State Drug Utilization Data

METHODOLOGY and EXAMPLE –

Step 1 – Extract the Units Reimbursed by Each State from the Medicaid State Drug Utilization Data File for 3Q2008 to 2Q2009

Each State's utilization data file is due to CMS no later than 60 days after the end of each quarter and is posted and updated on the CMS Web site on quarterly basis at: http://www.cms.gov/MedicaidDrugRebateProgram/SDUD/list.asp. The data elements included in this file are State, NDC, quarter and year, product name, units reimbursed, number of prescriptions, total amount reimbursed by State, amount reimbursed under Medicaid, and amount reimbursed by non-Medicaid. Although the drug utilization data is due to CMS no later than 60

days after the end of each quarter, it does not appear that this data is reliable until sometime after that since States often initially revise these submissions. Therefore, to better estimate utilization, we plan to use the past quarters' data, 3Q2008 to 2Q2009, in the calculation. Units reimbursed by NDC per State are then downloaded for each of the four quarters from 3Q2008 to 2Q2009.

Step 2 – Calculate the Average Total Units from 3Q2008 to 2Q2009

The Average Total Units are calculated by taking the average of the units reimbursed per NDC by State from 3Q2008 to 2Q2009. As with this step and all the following steps in this methodology, we are providing example to highlight the methodology. We are providing the following example for steps 2-9 to highlight the methodology.

NDC	3Q2008	4Q2008	1Q2009	2Q2009	Calculating the Average Total Units = Sum of Units / 4 Quarters	Average Total Units
00001-0001	150	50	90	110	= (150+50+90+110) ÷ 4	100
00002-0111	100	200	250	150	= (100+200+250+150) ÷ 4	175
00003-0222	500	300	100	350	= (500+300+100+350) ÷ 4	312.5

For the purpose of continuing this calculation into future quarters (e.g., 2Q2010 EQROA, 3Q2010 EQROA, and future quarters as necessary), we plan to calculate the average total units using quarters with the best available data on the total number of units reimbursed. Data will be moved forward one quarter for each subsequent EQROA. Thus for 2Q2010 EQROA, the average total units will be calculated using units reimbursed per NDC by State from 4Q2008 to 3Q2009. For 3Q2010 EQROA, the average total units will be calculated using units reimbursed per NDC by State from 1Q2009 to 4Q2009. And for 4Q2010 EQROA, the average total units will be calculated using units reimbursed per NDC by State from 2Q2009 to 1Q2010.

Step 3 – Identify the Drug Category of Each NDC

CMS posts the drug product data file on the CMS Web site on a quarterly basis at http://www.cms.gov/MedicaidDrugRebateProgram/09_DrugProdData.asp. This file can be downloaded to identify whether an NDC is a single source (S) drug, innovator multiple source (I) drug, or noninnovator multiple source (N) drug. The drug product information that goes into this file is based on manufacturer submissions to CMS. This file includes information such as NDC, drug category, DESI indicator, drug type, product name, etc. The most recent file posted on the CMS Web site is for 1Q2010. Please note that we plan to use the most updated drug product data file available for the quarter when we perform the calculation. For the purpose of calculating 1Q2010 EQROA, we are using 1Q2010 drug product data file.

Step 4 – Match the Drug Product Data File Against the 1Q2010 Quarter AMP File

Thirty days after the end of each rebate period, manufacturers are required to report to CMS their quarterly AMP and best price (BP) for each NDC on record with CMS. The most complete AMP and BP file that CMS has at this time is for 1Q2010. We plan to use the most updated

AMP and BP data received this quarter and all future quarters, as we believe this best represents the amount manufacturers will use as the basis for their increased rebate payments. Because 1Q2010 quarterly AMP and BP files and the drug product data file are two separate files that include separate information we need for each NDC, we plan to match both files by NDC in order to have both the quarterly AMP and BP and the drug category appear for each NDC to appear on the same file.

1Q2010 Quarterly AMP and BP File:		
NDC	Quarterly AMP	Quarterly BP
00001-0001	0.750000	0.650000
00002-0111	1.000000	0.800000
00002-0222	0.500000	0.000000

1Q2010 Drug Product Data File	
NDC	Drug Category
00001-0001	S
00002-0111	S
00002-0222	N

Matched Quarterly AMP File and Drug Product Data File			
NDC	Drug Category	Quarterly AMP	Quarterly BP
00001-0001	S	0.750000	0.650000
00002-0111	S	1.000000	0.800000
00002-0222	N	0.500000	0.000000

Step 5 – Determine Where AMP Minus BP Falls

Once we have matched the 1Q2010 drug product data file against the 1Q2010 quarterly AMP and BP file, we need to determine where the difference between AMP and BP falls. See details and example below.

For brand name drugs other than blood clotting factors and drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications:

A. If the difference between AMP and BP is less than or equal to 15.1 percent of AMP, then we plan to offset the full 8 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

B. If the difference between AMP and BP is greater than 15.1 percent of AMP, but less than 23.1 percent of AMP, then we plan to offset the difference between 23.1 percent of AMP and AMP minus BP.

C. If the difference between AMP and BP is greater than or equal to than 23.1 percent of AMP, then we do not plan to take any offset amount.

For brand name drugs that are blood clotting factors and drugs approved by the FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

D. If the difference between AMP and BP is less than or equal to 15.1 percent of AMP, then we plan to offset the full 2 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

E. If the difference between AMP and BP is greater than 15.1 percent of AMP, but less than 17.1 percent of AMP, then we plan to offset the difference between 17.1 percent of AMP and AMP minus BP.

F. If the difference between AMP and BP is greater than or equal to than 17.1 percent of AMP, then we do not plan to take any offset amount.

For generic drugs, we plan to offset an amount equal to two percent of the AMP (the difference between 13 percent of AMP and 11 percent of AMP), since these drugs are unaffected by best price.

Because we currently do not have the capability to systematically identify reformulated drugs, the additional rebate for those drugs is not included for now for the purpose of this calculation and no offset will be taken from the States at this point. Once these drugs are identified, we will include them in the EQROA for future quarters or the UROA process consistent with the provisions of section 2501 of the Affordable Care Act.

NDC	**Drug Category**	**Quarterly AMP**	**Quarterly BP**	**AMP–BP**	**AMP x 15.1%**	**AMP x 23.1%**	**Determination of Where AMP-BP Falls**
00001-0001	S	0.750000	0.650000	**0.100000**	0.113250	0.173250	Less than AMPx15.1% - use Step 5A above
00002-0111	S	1.000000	0.800000	**0.200000**	0.151000	0.231000	Greater than AMPx15.1% and less than AMPx23.1% - use Step 5B above
00002-0222	N	0.500000	0.000000	**N/A**	N/A	N/A	N/A – Generic drug

Step 6 – Identify the Offset Rebate Percentage to be Applied to Each NDC

Based on the identification of where AMP minus BP falls in Step 5, the following offset rebate percentage is applied to each NDC.

NDC	Drug Category	Determination where AMP-BP falls	Offset Rebate Percentage
00001-0001	S – brand	Less than AMPx15.1% - see Step 5A above	8%
00002-0111	S – brand	Greater than AMPx15.1% and less than AMPx23.1% - see Step 5B above	3.1%
00002-0222	N – generic	N/A	2%

Step 7 – Calculate UROA per NDC

Once AMP minus BP is determined (using the matched file with the 1Q2010 quarterly AMP and BP data and the drug category indicator for each NDC), we calculate the UROA by multiplying AMP by the offset rebate percentage determined in Step 5 for each of the category of drugs where that AMP minus BP is applicable. For generic drugs, the UROA is calculated by multiplying AMP by two percent.

NDC	Drug Category	Quarterly AMP	Offset Rebate Percent Applied	Calculating the UROA = Quarterly AMP x Offset Rebate Percent	UROA per NDC
00001-0001	S – brand	0.750000	8%	= 0.750000 x 8%	0.060000
00002-0111	S – brand	1.000000	3.1%	= 1.000000 x 3.1%	0.031000
00002-0222	N – generic	0.500000	2%	= 0.500000 x 2%	0.010000

Step 8 – Calculate QROA and Total QROA

To calculate the QROA, the average total units of an NDC are multiplied by UROA of that NDC. The total QROA is then calculated by taking the sum for all NDCs.

NDC	Average Total Units	UROA per NDC	Calculate QROA = Average Total Units x UROA	QROA
00001-0001	100	0.060000	= 100 units x 0.060000	$6.00
00002-0111	175	0.031000	= 175 units x 0.031000	$5.425
00002-0222	312.5	0.010000	= 312.5 units x 0.010000	$3.125
			Total QROA for All NDCs	**$14.55**

Step 9 – Discount Factor on Actual Payment Received from Manufacturers by State

When a State invoices a manufacturer, State may not receive the full payment from the manufacturer based on the amount the State invoices the manufacturer for that quarter in the following quarter. CMS has no current data to estimate the amount States received in payment from the manufacturers. Additionally, because of the zero URAs for 1Q2010, CMS is aware that States and manufacturers are attempting to develop a process to implement the new Affordable Care Act rebate provisions, and that States may have invoiced the manufacturers late, causing States to receive late payments from manufacturers. As a result, we plan to offset 25 percent of

the total QROA for 1Q2010 and 50 percent of the total QROA for 2Q2010, 3Q2010, and 4Q2010. We believe that this is the best estimation that we can propose at this time to avoid over-estimating the offset amount for States and inappropriately reducing rebates not related to this Affordable Care Act provisions. Since the EQROA will be reconciled with the total QROA for these quarters, the accurate offset amount will be determined ultimately.

Step 10 – Calculate EQROA per State

The EQROA is calculated by multiplying the total QROA by 25 percent for 1Q2010. For 2Q2010, the EQROA will be calculated by multiplying 2Q2010 total QROA by 50%. This will be the same for 3Q2010 and 4Q2010 EQROA.

1Q2010 EQROA = 1Q2010 Total QROA x Discount Factor of 25% = $14.55 x 25% = $3.64
2Q2010 EQROA = 2Q2010 Total QROA x Discount Factor of 50% = $X x 50%
3Q2010 EQROA = 3Q2010 Total QROA x Discount Factor of 50% = $Y x 50%
4Q2010 EQROA = 4Q2010 Total QROA x Discount Factor of 50% = $Z x 50%

Step 11 – Delivery of EQROA to State

We are aware that States are still developing a process to implement the new rebate provisions and adjust their systems to accommodate the new data. To minimize the burden for States, we plan to provide each State with their individual EQROA based on our calculation from the above methodology via a letter for each of the four quarters in 2010.

Step 12 – EQROA on CMS-64

To minimize the administrative work for States, CMS plans to populate the EQROA that CMS provides to each State on the CMS-64. This amount will be available for the State to view by September 30, 2010. Specific instructions on reporting rebate expenditures, including the line item number in which the EQROA will be populated, will be provided in the near future.

Step 13 – EQROA Reconciliation

Once CMS is able to provide States with the UROA based on the new rebate percentage, including the identification of the blood clotting factors, drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications, and the reformulated drugs, States will be able to reconcile the EQROA with the total QROA based on the units that States actually reimbursed for during the specific quarter.

TIMELINE

Our proposed timeline for these activities follows below. Please note that the dates and deliverables are only estimated and may be subject to change.

Estimated Date	Estimated Deliverable
September 7, 2010	Run most recently updated 1Q2010 AMP and BP data against most recently updated average units from 3Q2008 to 2Q2009.
September 28, 2010	Provide each State with their 1Q2010 EQROA via a letter.
September 30, 2010	CMS to populate State's 1Q2010 EQROA on the CMS-64.
October 1, 2010	Each State should be able to view their State's 1Q2010 EQROA in the CMS-64. This amount should be the same as the amount provided to the State in the letter.
November 15, 2010	Run most recently updated 2Q2010 AMP and BP data against most recently updated average units from 4Q2008 to 3Q2009.
December 1, 2010	Provide each State with their 2Q2010 EQROA via a letter.
December 30, 2010	CMS to populate State's 2Q2010 EQROA on the CMS-64.
January 1, 2011	Each State should be able to view their State's 2Q2010 EQROA in the CMS-64. This amount should be the same as the amount provided to the State in the letter.
February 15, 2011	Run most recently updated 3Q2010 AMP and BP data against most recently updated average units from 1Q2009 to 4Q2009.
March 1, 2011	Provide each State with their 3Q2010 EQROA via a letter.
March 30, 2011	CMS to populate State's 3Q2010 EQROA on the CMS-64.
April 1, 2011	Each State should be able to view their State's 3Q2010 EQROA in the CMS-64. This amount should be the same as the amount provided to the State in the letter.
May 3, 2011	CMS' systems ready to calculate the updated URAs based on the increased rebate percentage under the Affordable Care Act and the UROAs for 1Q2011.
May 4, 2011	CMS provides States with the 1Q2011 the Affordable Care Act URAs and UROAs.
May 16, 2011	Run most recently updated 4Q2010 AMP and BP data against most recently updated average units from 2Q2009 to 1Q2010 to calculate 4Q2010 EQROA.
June 1, 2011	Provide each State with their 4Q2010 EQROA via a letter. This will be the last EQROA CMS will provide to each State.
June 30, 2011	CMS to populate State's 4Q2010 EQROA on the CMS-64.
July 1, 2011	Each State should be able to view their State's 4Q2010 EQROA in the CMS-64. This amount should be the same as the amount provided to the State in the letter.
July 1, 2011	States may begin to report their 1Q2011 total QROA on the CMS-64.
August 1, 2011	Deadline for States to report their 1Q2011 total QROA on the CMS-64.
August 3, 2011	CMS calculates 2Q2011 URAs and UROAs. States should begin to reconcile the EQROA that CMS sends to States' against the total QROA based on actual units that States have received payment from manufacturers.
August 4, 2011	CMS provides States with the 2Q2011 URAs and UROAs.
October 31, 2011	Deadline for States to report their 2Q2011 total QROA on the CMS-64.

DATA LIMITATIONS

Please note the following EQROA data limitations:

- We used four quarters of utilization data rather than eight quarters to estimate utilization data as the shorter time period reduced the States' offset liability.
- We excluded S/I NDCs that did not have AMP and BP reported and N NDCs that did not have AMP reported. Despite the fact that the manufacturers did not report their data in a timely manner to CMS, they still are required to pay timely rebates to the States. Because their data are not reflected, the offset amount is underestimated.
- We excluded NDCs that do not have units reported. Similar to late reporting by manufacturers, where there were units billed to the manufacturers, this underestimates the offsets.
- We have identified the blood clotting factors and exclusively approved pediatric drugs with the best available data at the time the calculation is performed; therefore, the offset amount may change as more data become available. We believe this will have a minimal effect on the offsets.
- We have yet to identify reformulated drugs; therefore, we did not apply the increased additional rebate amount to the EQROA. This action underestimates the offsets for those drugs, provided that the manufacturer made reasonable assumptions for reformulated drugs.
- The EQROA does not include rebates and units from MCOs as we do not yet have that utilization data. To the extent that most States have been unable to provide the MCO utilization data to the manufacturers, these data are not accounted for in the estimated offsets. For any States that were able to provide utilization data, the offsets will be underestimated. While more States will be able to report this utilization data for subsequent quarters, we will not include these data until they are included in the States utilization data that we use to calculate the EQROA, or until the QROA process is in place.
- We do not have current estimates of rebates collected by quarter since the rebates reported in any given quarter always include amounts for past quarters. As a result, we are not able to estimate the amount States will actually receive in rebates for 1Q2010 or when they will receive them. We assumed that, in accordance with guidance we provided, manufacturers calculated and submitted their URAs to the States based on the Affordable Care Act rebate percentage. We believe we conservatively estimated a minimal percentage of 25 percent for 1Q2010 EQROA and 50 percent for 2Q2010, 3Q2010, and 4Q2010 EQROA. To the extent that the States receive timely rebates for these quarters at a greater or lesser rate, this approach will underestimate or overestimate the offset.