

**Responses to Comments Received
Federal Register Notice on a Revised Collection;
“Survey of Retail Prices: Payment and Utilizations Rates,
and Performance Rankings”**

(Form number CMS-10241)

CMS received five comments on the March 2, 2012 final 30-day notice on the revision of a currently approved collection; “Survey of Retail Prices: Payment and Utilization Rates, and Performance Rankings” (Form number CMS-10241). The five commenters included two pharmaceutical associations, a biopharmaceutical company, a biotechnology company, and a provider of pharmaceutical care.

1...Authority to Collect Data

Commenters stated that CMS is not authorized by Congress to collect and distribute National Average Drug Acquisition Cost (NADAC).

The commenters believe that Congress has authorized CMS to create a specific benchmark and that Average Manufacturer Price (AMP) is one of several such authorized benchmarks. The commenter commented that CMS should concentrate on properly implementing the AMP benchmark that Congress actually authorized.

CMS Response

The data will provide information which CMS expects to use to assure compliance with Federal requirements. Section 1927(f) provides, in part, that CMS may contract with a vendor to conduct monthly surveys of retail prices for covered outpatient drugs. The statute provides that such prices represent a nationwide average of consumer purchase prices, net of discounts and rebates. The statute further contemplates that the contractor provide notification when a drug product becomes generally available and that the contract include such terms and conditions as the Secretary shall specify, including a requirement that the vendor monitor the marketplace. We have included terms in our vendor contract to obtain additional information regarding marketplace prices (including pharmacy prices), which would be provided on a voluntary basis.

We expect that ingredient cost data would provide information to assist CMS in carrying out its responsibilities and to the States in setting drug payment rates. This NADAC file will allow for covered outpatient drugs to be reimbursed more effectively.

We will also continue to assess AMP data in order to establish accurate FULs, consistent with the statute.

2...Alternative Data Submission from Wholesalers

A commenter expressed the opinion that CMS should allow pharmacy wholesalers to submit NADAC data to the agency to reduce the burden on small pharmacies.

CMS Response

A pharmacy may authorize their wholesaler to submit the monthly invoicing data directly to the contractor employed by CMS for this project.

3...NADAC Data Determination and Communication

A commenter stated that CMS needs to make clear that the NADAC data are outdated because the invoices used to calculate the NADAC data might be several months old and do not reflect real-time purchasing costs to independent pharmacies. The commenter asked that CMS include the month for which the data were collected. The commenter suggested that CMS compare the NADAC data to the Federal Upper Limits (FULs) and not set the FULs any lower than the NADACs for multiple source drugs. The commenter further stated that CMS should indicate on the public website how it is averaging the invoice data collected, given the single NADAC amount for a drug will include purchasing costs from independent and chain pharmacies, and indicate the median for each drug.

CMS Response

We appreciate these concerns and expect to provide additional information regarding the methodology for calculating the NADAC on our website. In addition to the initial Stakeholders' Meeting held on August 4, 2011, CMS intends to hold a follow-up Stakeholders' Webinar to review the methodology utilized for the NADAC calculation. The retail price survey mailbox (rsp@cms.hhs.gov) will also be available for questions.

We do not believe that in light of the timeframes established in the survey, the data will be outdated. CMS does intend to post the month from which data were collected. We also appreciate the comments on the comparison to FULs and we will look at these prices in comparison to the FULs once this data is available, although we do not currently intend to adjust the FUL prices based on these NADAC prices.

4...NADAC should show purchasing costs by pharmacy type

Commenters stated that CMS will be analyzing variation in the NADAC between chain and independent pharmacies, and urban and rural pharmacies. The commenters requested that the definitions of these pharmacies be explained and transparent.

CMS Response

CMS intends to evaluate the variations between chain and independent pharmacies, urban and rural pharmacies, and retail community and specialty pharmacies. As previously stated, CMS intends to hold a follow-up Stakeholders' Webinar to review the methodology utilized for the NADAC calculation.

5... NADAC and Dispensing Fees

Commenter stated that States will receive the NADAC data but not be required to use the data to set Medicaid reimbursement. The commenters also stated that CMS would not approve the use of NADAC unless a State is also increasing its dispensing fee.

CMS Response

CMS hopes to publish the NADAC file as a pricing reference for States. It is up to the States to decide if they want to use the NADAC file as a pricing metric in the determination of pharmacy reimbursement. We agree that a State which decides to use the NADAC in calculating pharmacy reimbursement will be required to go through the SPA process and receive federal approval of the SPA to ensure compliance with Federal requirements, including the requirements concerning dispensing fees.

We understand the importance of States setting reasonable dispensing fees and we have defined the dispensing fee in current regulations.

6...Rebates, Discounts, Chargebacks and other Free Goods

One commenter stated that CMS' contractor will conduct a separate survey of community pharmacies at least annually that will ask for rebates, discounts, chargebacks and free goods that are not typically included on pharmacy invoices.

CMS Response

We intend to address the concerns regarding off-invoice prices in a separate document. This data will be evaluated to determine pricing accuracy.

7...Data Request

One commenter stated that it is not clear if CMS or Myers & Stauffer, LC will be contacting the pharmacies about the data. The commenter also requested that CMS allow time for associations to notify and educate pharmacies about this survey.

CMS Response

CMS' contracted vendor, Myers & Stauffer, LC, will be sending a letter regarding the retail price survey. CMS provided adequate time to educate pharmacies regarding this voluntary survey; for example, a Stakeholders' Meeting was held at CMS on August 4, 2011 to begin the education process. In addition to the information posted on CMS's website, it has also provided information through the Federal Register s.

8...Confidentiality

Commenters stated that concern has been raised regarding how the data will be protected from potential disclosure and that pharmacy contracts with wholesalers may preclude them from disclosing these data.

CMS Response

It is important to note that all drug purchase price information submitted for this project will remain under the control of CMS, will only be used for the purposes described above, and will remain secure to the extent provided by law, consistent with Exemption 4 of the Freedom of Information Act (FOIA).

Accordingly, neither CMS nor Myers and Stauffer will release invoice information and pharmacy identification that is submitted voluntarily and is identified by you as proprietary, except as is required by law.

9.... Variation in data

One commenter stated that the NADAC file should indicate the percentage changes from the previous month, along with historical data from the previous twelve months. The commenter also requested that the NADAC be compared to the Average Manufacturers Price (AMP) to determine if there are wide discrepancies between the two numbers.

CMS Response

CMS intends to update the NADAC data as a full replacement file each month on the CMS website. Percentage changes from previous postings are not planned to be published, however we will look at posting interim price change updates throughout the month. Because the AMPS are confidential and may not be publicly disclosed, CMS does not plan to publicly compare NADAC pricing to AMP.

10.... Appeal Mechanism

A commenter suggested that CMS provide an appeal mechanism for the NADAC and asked if the States that decide to use this data will need to update their files each time the NADAC file is updated.

CMS Response

We note that NADAC will be another source of information that the States can consider using to determine Medicaid payment rates and as such, States should consider the merits of using this data. We would expect that States may consider an appeals or exception process concerning the use of such prices, as may be necessary, for those States that decide to use this data. The data will be posted on the CMS website for usage.

11...Inadequate Data Collection

Two commenters expressed concern regarding the NADAC assigned for drugs in which adequate data was not collected.

CMS Response

The threshold response for each NDC will be determined upon collection of the data. The data from each sample will be analyzed to determine the statistical reliability of the information. Where it is determined that the data will not support a NADAC for a drug, one will not be published.

12...340B Invoices

A commenter stated that 340B invoices should be excluded from this survey.

CMS Response

CMS agrees; drugs identified as purchased through 340B on invoices will not be included in this survey.

13...Pharmacy Invoice Accuracy

One commenter stated that many pharmacies do not have invoices that are only limited to the drug ingredient cost as required by the “NADAC Survey Request for Information” document. The commenter believes that this requirement will prevent these pharmacies from being able to respond to the survey and creates a strong disincentive for pharmacies to respond to the survey. The commenter further states that pharmacies that submit “drug purchase records” and “photocopy existing records” as directed by CMS guidance may include other costs such as shipping, warehousing, and other administrative costs. Consequently, pharmacies could be accused of making false statements in an effort to inflate NADAC values. The commenter believes that pharmacies making a good effort to provide acquisition cost information should receive liability protection.

CMS Response

CMS is requesting that pharmacies completing this voluntary survey submit their invoices to include drug ingredient costs covering the most recent 30-day period. Other information sent on the invoices not relating to drug ingredient costs, such as shipping, warehousing, and other administrative costs, will be evaluated by the contractor and excluded from this survey.

14... Burden

Two commenters disagree with CMS’ estimate that individual pharmacies will be able to complete the survey in thirty minutes or less and believe that complying with this information request will be significantly more burdensome for retail community pharmacies. The commenters believe that multiple factors could affect this, such as the survey being distributed to individual pharmacies, when in the case of chain pharmacies, individual pharmacy locations do not have information about drug acquisition cost. There was also concern that the requested 14-day response time is insufficient, given the amount of time that will be needed to comply with the information request.

CMS Response

This survey is voluntary and is described as such on the survey instrument tool. We believe the collection of data estimate of less than 30 minutes of a non-pharmacist’s time to complete is reasonable as we are only asking for copies of invoices to be submitted. We also believe that chain pharmacies will be able to work out the logistics of supplying this information with their individual pharmacies and will be able to produce this data in a similar timeframe since we understand there are chain centrally-located operations centers that can facilitate the voluntary submission of individual store data.

We believe the 14 day timeframe is reasonable given the scope of information being supplied and note that allowing more time would further risk the resultant data being untimely. It is within the discretion of the responders to determine whether pharmacist or non-pharmacist staff will produce the data in response to the survey instrument. CMS presumed that non-pharmacy staff would be appropriate in completing the survey since CMS is requesting only photocopies of invoices.

The burden in this estimate is only for the collection of the NADAC information. We expect that the adequacy of the sample size and the month-to-month collection of data processes will be further

specified within the publication of the methodology, which we expect to publish on the CMS website, and that issuance should pose no burden on the responders.

We also determined the estimates concerning time and burden, as well as the personnel used to complete this survey, was reasonable based on the contractor's experience in coordinating voluntary collections of invoice information from pharmacies. For example, the contractor has a history in collecting price information and is currently performing State studies involving the collection of invoice information with two States.

15... Publishing of Monthly NADAC

Two commenters stated that the data that CMS publishes as the monthly NADAC will be lagged by at least two months, and that CMS needs to update the data for brand drugs based on changes in the published WAC price if there are price increases in-between the surveys.

CMS Response

CMS does not believe that in light of the timeframes established in the survey, the data will be outdated. CMS intends to consider reflecting price changes in WAC in the NADAC, to be applied throughout the month. The NADAC will be adjusted based on information gathered from the next survey responses.

CMS intends to publish the methodology utilized for the calculation of the NADAC on the CMS website.

16...Importance of Comprehensive Pharmacy Reimbursement

One commenter stated that there are multiple components in pharmacy reimbursement, to include drug ingredient costs and dispensing fees. They hoped CMS would evaluate dispensing fees in States those chose to use NADAC as a benchmark for pharmacy reimbursement.

CMS Response

CMS agrees. If a State chooses to use the NADAC as a benchmark for pharmacy reimbursement, the State will be required to go through the State Plan Amendment (SPA) process and State dispensing fees will be evaluated.

17...Specialty Pharmacies

Commenters questioned how CMS defines specialty pharmacies and how specialty pharmacies are differentiated from mail order pharmacies.

CMS Response

Specialty pharmacies are those retail community pharmacies that predominantly dispense specialty drugs. Specialty pharmacies conduct business as a retail community pharmacy inasmuch as they dispense medications to the general public at retail prices and are licensed by the State as a pharmacy. Specialty pharmacies are identified by their National Provider Identification Number. Specialty pharmacy information will be separately compiled and we plan to post the methodology utilized to develop NADAC on the CMS website.

18...NADAC Development Process

Two commenters stated that CMS should explicitly and publicly define its methodology for the development of NADAC and implementation process. The commenters stated that CMS should specify the pharmacies included in the survey and be very clear in describing it to the public. The commenters also want CMS to specify how pharmacy price concessions will be included or otherwise applied to determine NADAC (including rebates and discounts), and to lay out a specific timeline to address and incorporate public feedback.

CMS Response

This survey is designed to collect invoice data on a voluntary basis from a sample of retail community pharmacies throughout the country. We intend to post on our website the methodology utilized, as well as the results of the survey calculations. In addition, CMS expects to hold a webinar with the Stakeholders after the methodology is developed, to give another opportunity for comments. Pharmacy price concessions will be addressed at a later time.

19...NADAC as a State Reimbursement Methodology

A commenter stated that they hoped CMS would encourage States to use NADAC and retire state-specific average acquisition cost metrics. The commenter was concerned that should CMS finalize and publish NADAC, the publication of federal and state-specific average acquisition cost metrics could cause confusion.

CMS Response

CMS plans to develop a NADAC for States to consider when setting their reimbursement methodology. It is up to the States to decide if they want to move to NADAC for pharmacy reimbursement and whether they want to retire their State-specific metrics. Even if a State keeps its current State-specific data, as long as it is clearly identified and the State specifies what data it is using in setting its payment rates, we do not agree that it will cause confusion. If a State chooses to use the NADAC as a reimbursement benchmark, the State will be required to go through the State Plan Amendment (SPA) process.

20...Mail-Order Pharmacy Pricing

One commenter questioned how States that use NADAC should handle mail-order pharmacy pricing.

CMS Response

Mail-order pharmacies are not included in this survey and therefore will not be included in the development of NADAC. Only mail-order drugs supplied regularly through specialty pharmacies will be included in determining the NADAC.

21... Manufacturers Shipping Directly to Patients

One commenter inquired how transactions where the manufacturers ship drugs directly to patients once a payer adjudicates the claim, e.g. Medicaid, be classified.

CMS Response

Drug distributors that ship directly to patients, and are retail community pharmacies, will not be included in the development of NADAC.

22...Hospital Pharmacies

One commenter questioned how CMS proposed that States that use NADAC to set EAC handle payment for drugs dispensed to outpatients at hospital-owned pharmacies, which are not included in the calculation of NADAC.

CMS Response

Given the scope of the survey, we do not expect that states would use the data for hospital owned pharmacies.

23...Non-Retail Channels

One commenter expressed concern regarding how CMS would address drugs which are commonly acquired through non-retail channels that may not have adequate survey observations recorded to calculate a NADAC for the drug groupings. The commenter also asked whether CMS would require a minimum number of records per drug grouping in order for a NADAC to be published or updated from an earlier published NADAC.

CMS Response

Similar to the previous response, the threshold response for each NDC will be determined upon collection of the data. The data from each sample will be analyzed to determine the statistical reliability of the information. Where it is determined that the data will not support a NADAC for a drug, one will not be published.

24... Complete and Accurate Survey Responses

A commenter asked how CMS would verify that pharmacies are not “gaming” NADAC and only submitting their most expensive invoices. The commenter further stated that the error rate by pharmacies submitting Medicaid claims suggest that there is a high probability of mistakes (clerical and otherwise) when submitting survey results and asked how CMS intended to mitigate this risk. A commenter was also concerned that monthly responses to the survey be sufficiently representative so that NADAC provides for adequate reimbursement.

CMS Response

By reviewing actual invoices nationwide, we will get information that will help us identify outlier pricing such as a pharmacy’s most expensive invoices. We do not intend to provide the criteria by which we suspect that pharmacies are gaming the survey or sending their most expensive invoices as we believe that would be counterproductive to identifying and preventing further such actions.

We also note that with the large sample size, isolated instances of prices that may be outliers would have minimal impact on the final NADAC rate. However, we expect to examine these specific outliers and their potential impact in calculation of the NADAC. We do not believe that there will be a high probability of mistakes since pharmacies only need to copy actual invoices and submit them as their survey response. Based on the experience of our contractor, we believe the sample sizes will be sufficient to determine the NADAC and that States will consider it as another measure of determining the proper Medicaid payment for covered out-patient drugs.

25...Personnel to Complete Survey

One commenter asked who is a non-pharmacist and what quality controls will be used to ensure that “non-pharmacist” staff members have the appropriate skills and knowledge to respond correctly to these surveys that could impact reimbursement. The commenter further question whether a pharmacy technician or even an intern could provide survey data to Myers and Stauffer.

CMS Response

We have not further identified non-pharmacist staff members and leave it up to the individual pharmacy to determine who can appropriately respond to the survey. But we again note that only a copy of an invoice from the past 30-days is required to complete this voluntary survey and there is no further interpretation of data needed. However, to the extent that a respondent believes this data should be further reviewed by a pharmacist, we encourage them to do so. Even in such an event, we believe that such a review will not be lengthy such that it would add to the time estimate nor would a pharmacist’s review necessarily be ongoing once the pharmacist is comfortable that the non-pharmacist staff member is sending the correct information in response to the survey.

26... Appeals and Disputes

A commenter suggested that CMS provide an appeal mechanism for the NADAC that is available to all stakeholders. The commenter believes that it is critical not only to pharmacies that the NADAC is accurate but also to other stakeholders, including manufacturers who want to ensure that pharmacies are reimbursed appropriately to ensure access for patients. The commenter questioned whether there will be a dispute process available for stakeholders, other than pharmacies, to challenge the calculated NADAC.

CMS Response

We note that NADAC will be another source of information that the States can consider using to determine Medicaid payment rates and as such, States should consider the merits of using this data. We would expect that appeals or exceptions concerning the use of such prices would be raised, as may be necessary, to the States that decide to use this data.

27...Letter to the CMS Administrator Concerning a Proposed Rule CMS-2328-P

One commenter sent us a letter written to the CMS Administrator regarding a proposed rule entitled “Medicaid Program; Methods for Assuring Access to Covered Medicaid Services.”

CMS Response

While we appreciate this information, it is beyond the scope of our request for comments on the burden estimate and we therefore will address these comments in a different venue. This letter was unrelated to matters addressed in this PRA package.