

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 a number of comments on the September 30, 2011 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 nine commenters included pharmacy schools, manufacturers, and pharmaceutical associations.

Necessity to Collect Data

One commenter inquired if consideration had been given to using existing information sources and not undertaking additional effort and cost of another market-based survey. The commenter encouraged CMS to investigate the possibility that an existing mechanism might serve their needs. The commenter further stated that there is a vendor that has audited wholesaler sales to pharmacies and has pharmacy acquisition costs readily available for purchase.

CMS Response

CMS researched the availability of actual acquisition cost data and determined that the best source of obtaining accurate data is to survey retail community pharmacies directly. The contractor that was selected for this survey has extensive experience in developing and designing acquisition cost based models for pharmacy ingredient reimbursement.

Authority to Collect Data

Several commenters stated that CMS is not authorized by Congress to collect and distribute National Average Drug Acquisition Cost (NADAC). A commenter believes 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 it 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 the States in setting drug payment rates.

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

Alternative Data Submission from Wholesalers

Another 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 CMS.

Burden

One commenter requested that CMS make clear to pharmacies in the survey instrument that providing the data to CMS is voluntary. Another commenter disagrees with CMS' estimate that individual pharmacies will be able to complete the survey in thirty minutes or less and believes that complying with this information request will be significantly more burdensome for retail community pharmacies. The commenter believes 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. Another concern was that due to the complexity and importance of the information being collected, this task will not be delegated to a junior employee. Also noted was that many pharmacies are already complying with the requirements of several states to submit invoices for the calculation of acquisition benchmarks, the estimated burden does not take into account the duplicative nature of the CMS survey; and CMS' request for pharmacies to participate in an additional survey related to NADAC suggests that complying with this survey request will involve significantly more time than thirty minutes and thereby believes that the estimates prepared by CMS is inaccurate.

Another commenter expressed the opinion that CMS has not provided a definitive response regarding what is an adequate sample. A commenter expressed concern regarding whether the responses on a month to month basis will be adequate.

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.

Since these surveys are a sample of retail community pharmacies on a nationwide basis, we think the likelihood of multiple requests over any significant amount of time is unlikely.

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 part will 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, since the contractor has had 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.

NADAC Data Determination and Communication

Two commenters 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 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 in our website. We do not believe that in light of the timeframes established in the survey, the data will be outdated. 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.

NADAC State Reimbursement Methodology

A commenter stated that CMS should not allow States to use NADAC data for pharmacy reimbursement unless CMS approves and maintains as part of the State Plan Amendment (SPA) approval a state dispensing fee that corresponds to the pharmacy costs of dispensing Medicaid prescriptions in the state, based on accurate cost of dispensing studies. A commenter stated that CMS must make clear to States that in order to maintain patient access to pharmacies, dispensing fees must be reviewed and adjusted to reflect no less than the true cost of dispensing prescription medications to Medicaid patients. The commenter further stated that States that choose to use NADAC as a benchmark for pharmacy reimbursement must also base payment to pharmacies for dispensing prescription medications on the true cost to pharmacies. Another commenter encouraged CMS to provide States with clear guidance on how they can translate NADAC into an appropriate reimbursement formula that complies with CMS'

regulations on Medicaid drug payments. The commenter further states that regardless of the final NADAC methodology adopted by CMS, they hope that CMS will provide guidance to State Medicaid programs on how to use the metric in creating their pharmacy reimbursement formulas.

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 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 to provide payment for the pharmacy's costs of dispensing a drug.

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.

Another commenter urged CMS to collect data regarding off-invoice price concessions, such as rebates or other discounts on a monthly basis, and to incorporate this data in the NADAC metric so that it more closely reflects pharmacies' net drug acquisition costs. The commenter believes that including off-invoice discounts in NADAC would make it simpler for States to use NADAC data in developing accurate reimbursement formulas. A commenter requested that CMS clarify the intended use of the collected data on price concessions, e.g., rebates and other off-invoice discounts and how will this information be integrated with the NADAC and/or Retail Price Survey data. The commenter also requested clarification regarding the frequency that the survey will be conducted, whether the results will be published, and if so, whether the published data will be aggregated or released in a way that identifies the price concessions provided by a specific manufacturer.

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, such as shipping, warehousing, and other administrative costs will be evaluated by the contractor and excluded if it does not relate to ingredient cost.

The concerns regarding off-invoice prices and use of the data will be addressed in a separate document, which we expect to publish on the website.

Confidentiality

Several commenters expressed concern regarding the conflicting information in the draft information collection request pertaining to the confidentiality of information submitted by pharmacies. They believe that strong and clear confidentiality protections, including a strong confidentiality agreement between CMS and Myers and Stauffer, must be in place to ensure that individual company invoice price data are not revealed. Another commenter expressed concern regarding the possibility of data collected under the NADAC being shared with other government entities despite the confidentiality requirements under Myers & Stauffer's contract with CMS. The commenter requested that CMS publish a draft of the controls which will prevent data from being shared across government entities for public comment to allow stakeholder input before issuing final guidance. One commenter suggested that CMS provide details regarding whether pharmacies will be assured of confidentiality to encourage participation in the survey.

CMS Response

It is important to note that all drug purchase price information submitted for this project will remain under the control of CMS, and will remain confidential, consistent with Exemption 4 of the Freedom of Information Act (FOIA). Consistent with such provisions, the information will be maintained by us. CMS will not release information identified as confidential to the public. We do not intend to share the data with other government entities.

Beneficiary Access

One commenter was concerned with Medicaid beneficiaries' access to drugs, if a State's reimbursement methodology would change.

CMS Response

Any State that uses this data for payment purposes must meet all Federal requirements for doing so. For proposed reimbursement changes, States would need to submit a State Plan Amendment (SPA), consistent with the regulations, to implement reimbursement changes using this data. Additionally, the State must demonstrate and assure to CMS that beneficiary access is maintained.

NADAC as a State Reimbursement Methodology

Several commenters stated that they hoped CMS would encourage States to use NADAC and retire state-specific average acquisition cost metrics. One 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, the State will be required to go through the State Plan Amendment (SPA) process.

NADAC Development Process

One commenter stated that CMS should explicitly and publicly define its methodology for the development of NADAC and implementation process. The commenter stated that CMS should specify the pharmacies included in the survey and be very clear in describing it to the public. The commenter also wants CMS to specify how pharmacy price concessions will be included or otherwise applied to determine NADAC (including rebates and discounts, and for CMS 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 hope to post on our website the methodology utilized, as well as the survey calculations. In addition, CMS expects to hold a teleconference with the Stakeholders after the methodology is developed, to give another opportunity for comments. Pharmacy price concessions will be addressed in another document.

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. Rather, we expect that States would set a separate pricing methodology for mail-order drugs.

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 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.

CMS expects to distinguish the difference between specialty pharmacy and mail-order pharmacies on the CMS website.

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

Drugs that are shipped directly to patients will not be included in the development of NADAC.

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.

Inadequate Data Collection

One commenter 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. Since drug cost data can be tightly clustered, even small sample sizes may be statistically reliable. 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.

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. Since drug cost data can be tightly clustered, even small sample sizes may be statistically reliable. 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.

Complete and Accurate Survey Responses

Commenters 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. As we previously stated, since we believe that drug price data can be tightly clustered, even small sample sizes may be statistically reliable. 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.

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.

Additional NADAC Survey

Several commenters questioned the sample size and completion time for an additional NADAC survey that the contractor described at the August 4, 2011 Stakeholder’s meeting. Clarification was requested for more detail on the specific methodology for this additional survey.

CMS Response

The additional survey discussed the collection of discounts and rebate information. This survey will be addressed in a separate Federal Register notice and we also expect to include more details concerning this process on our website.

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.

Renaming “NADAC”

A commenter suggested that unless discounts, rebates, and charge backs are included in the reported average prices, the data resulting from the survey cannot be accurately called an “average acquisition cost.” The commenters believes that the figure computed from the survey data should be called either the “NADIP” (National Average Drug Invoice Price) or “NADIC” (National Average Drug Invoice Cost) so that all stakeholders understand what the figure represents.

CMS Response

We appreciate this comment, but we believe that NADAC will sufficiently describe the acquisition costs for covered outpatient drugs and its limitations. We expect to describe the methodology under which it is collected on our website. .

Timeline for the Survey Process and Reporting of NADAC

One commenter requested that CMS publish a specific timeline for the survey process and public reporting of the NADAC. The commenter further request clarification regarding the timing of the monthly survey process, including the timing of issuance of surveys, submission of data by pharmacies, the generation and publication of the NADACs, when the first NADACs will be released for possible use by state Medicaid programs, as well as the format in which the NADACs will be published. The commenter also urged CMS to publish a draft version of the format for public comment to allow stakeholder input before final guidance.

CMS Response

We do not have a specific timeline at this time. We hope to begin collecting this information as soon as possible and publish it promptly after we have collected it. We also expect to post information on the methodology on our website as soon as possible. While we will further consider publishing a draft

version of the format, we do not plan to do so at this time as doing so would further delay releasing this data.

NADAC as a Reimbursement in Non-Pharmacy Settings

One commenter requested that CMS instruct States not to use NADAC to set reimbursement rates in a non-pharmacy setting, e.g., a drug sold to a physician's office or a clinic as well as a specialty pharmacy where the invoice or acquisition costs are likely to be different.

CMS Response

As we have previously stated, we expect that States will consider these prices for retail community pharmacy settings and we do not expect them to use these prices for non-pharmacy settings. We expect to further specify this methodology on the CMS website.

Low-Volume Drugs

One commenter commented that certain drugs that are dispensed by retail and specialty pharmacies in low volumes should be excluded from the survey due to the likelihood that the small sample size for these drugs will produce unreliable pricing information. The commenter requested that drugs that are not generally dispensed through a retail community pharmacy be excluded from the NADAC survey. The commenter further requested that CMS work with stakeholders to identify these low-volume drugs so that they can be excluded from the survey.

CMS Response

The threshold for each NDC will be determined upon collection of the data. Since we believe that drug pricing data can be tightly clustered, even small sample sizes may be statistically reliable. 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.

CMS Stakeholders Meeting

One commenter sent in recommendations, concerns and questions regarding the August 4, 2011 meeting at CMS that was not in response to the Federal Register notice.

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.

Representative Sample of Valid Information

Several commenters questioned what constitutes an adequate sample for this survey. A commenter stated that the contractor plans to survey 2,500 pharmacies each month and conduct separate monthly surveys of independent/chain and specialty pharmacies and asked that CMS publish the data source that will be used to identify and classify pharmacies, as well as detail the process that will be followed to

prevent skewed results. Another commenter indicated that Myers & Stauffer will provide CMS with NADAC, regardless of the size of the response sample, but the information would have less validity as a metric if there were a lower response rate.

CMS Response

CMS' contractor has extensive experience with ensuring that a statistically significant sampling is represented for this survey. As we previously responded, we expect to put the methodology regarding the survey on our website.

Appeal Mechanism

Several commenters suggested that CMS provide an appeal mechanism for the NADAC that is available to all stakeholders. One 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. One 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 concerning the use of such prices would be raised, as may be necessary, to the States that decide to use this data.

Federal Supply Schedule Prices

One commenter requested that CMS confirm its understanding that because the Federal Supply Schedule pricing is only available for certain government entities and is not available for the retail pharmacy that such pricing would not be part of the survey

CMS Response

Federal Supply schedule prices will not be included in this survey.

Authorized Generics

One commenter stated that CMS should clarify how authorized generics will be treated in a drug group and how they are defined.

CMS Response

Each NDC, including single-source and multi-source drugs, will be assigned a NADAC. Authorized generics will be included with their therapeutic equivalents.

NADAC for 5i Drugs

One commenter stated that most of its product line consists of drugs that are used through inhalation, infusion, injection, implantation, and instillation (the 5i drugs) that may be provided by specialty pharmacies but most have very little or no retail business. (5i.) However, they receive Medicaid rebate claims for these products as physician administered drugs. The commenter contended that the draft weighted AMPs that were published only included certain 5i drugs. The commenter questioned whether there will be any effort to determine a NADAC for 5i drugs or will the States have to rely on the average weighted AMPs/FULS or some other pricing metric to set reimbursement for these products.

CMS Response

The 5i drugs that have sufficient retail community pharmacy sales as reflected in the surveys will be included and will receive a NADAC. Those that do not will not receive a NADAC.

Drug Categories

One commenter asked how products will be grouped for NADAC determinations and if any one compendium product groups will be used. There was concern that CMS files would not distinguish between the innovator product and an authorized generic product. The commenter suggested that a way to ensure accuracy is to establish a drug category specifically for them. The commenter asked if the drug groupings would be product-based rather than drug category-based and would the product groupings be consistent with those used for the weighted AMPs/FULs.

CMS Response

We expect to have the drug groups detailed and listed within the methodology posted on the CMS website.