

**Submitter :** Tish Hollingsworth  
**Organization :** Kansas Hospital Association  
**Category :** Health Care Provider/Association

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1380-Attach-1.DOC



February 20, 2007

Leslie Norwalk  
Acting Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***Re: (CMS-2238-P) Medicaid Program: Prescription Drugs, Proposed Rule, (Vo. 71, NO. 246),  
December 22, 2006***

Dear Ms. Norwalk:

The Kansas Hospital Association (KHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule implementing provisions of the *Deficit Reduction Act of 2005* (DRA) that pertain to the Medicaid prescription drug program. Our comments address CMS' interpretation of Section 6002 of the DRA and the new requirement that hospitals report physician-administered drugs using the National Drug Code (NDC). We will focus on two issues:

- the legal premise upon which CMS has based its interpretation of Section 6002, and
- the significant administrative burden these new reporting requirements impose on hospitals, specifically Kansas' experience to date with our State Medicaid Agency.

**FFP: CONDITIONS RELATING TO PHYSICIAN-ADMINISTERED DRUGS – SECTION 447.420**

Section 6002 of the DRA added a new requirement to the Medicaid statute specifically to enhance the ability of state Medicaid programs to secure rebates from drug manufacturers under the Medicaid drug rebate law. This section ties Medicaid rebate payments for covered outpatient drugs that are physician administered, as determined by the Secretary, to “the collection and submission of such utilization and coding data (such as J-codes and NDC numbers) ...as necessary to identify the manufacturer of the drug.” The data collection requirement extends to both single and multiple source drugs. However, in the proposed rule, CMS does not define “outpatient drugs that are physician administered” as the statute clearly states that the Secretary must do. Instead, the rule's preamble indicates that CMS intends to interpret Section 6002 to

require submission of the NDC numbers for outpatient drugs furnished as part of a physician's service to Medicaid beneficiaries in hospital outpatient clinics and departments – not solely in physicians' offices. CMS' proposal to apply Section 6002 so broadly is wrong. It is not supported by the statute's plain language, is inconsistent with congressional intent, and would nullify the *Social Security Act of 1965* exemption of hospital outpatient clinics and departments from Medicaid rebate program obligations.

**Section 6002 does not apply to outpatient drugs administered in hospital outpatient clinics and departments.**

Section 6002 requires only the collection of utilization and coding data for drugs that are subject to a rebate requirement under Medicaid statute provisions that predate the DRA – a position that CMS acknowledges in the proposed rule. Under Section 6002, state Medicaid programs are expressly directed to provide for the submission and collection of drug utilization and coding data “as necessary to identify [manufacturers of drugs] in order to secure rebates” under the Medicaid rebate law. In other words, the data collection requirement applies only if the state Medicaid agency finds it necessary to obtain a drug's NDC number in order to identify the responsible manufacturer and enforce a Medicaid rebate payment obligation. On the other hand, for outpatient drugs that are not subject to a rebate payment requirement – like those dispensed in hospital outpatient clinics and departments – the collection of NDC information with respect to that drug plainly is not necessary to securing a rebate, and the law does not require submission or collection of NDC data on the drug.

The statutory language, in fact, does not directly compel states to collect only NDC information on drugs subject to the rebate requirement. While reporting of the NDC numbers is preferred after January 1, 2007, the statute clearly authorizes the Secretary to allow for an alternative coding system. The statute states that the purpose of the data collection is “as necessary to identify” the manufacturer of the drug in order to collect Medicaid manufacturer rebates. The statute mentions J-codes and NDC numbers as examples of the type of “utilization and coding data” that could be collected. To the extent that J-codes can be used to identify a drug for Medicaid rebate purposes, continued use of J-codes to identify drugs is consistent with statutory compliance.

Further, the Secretary is authorized to delay applying the data reporting requirement in order to prevent hardship to any states that require additional time to implement the reporting system. Such hardship is not expressly limited in the statute and may encompass the state's consideration of difficulties in obtaining data from reporting hospitals and the time needed to reconfigure the systems of reporting hospitals.

**Section 6002 was enacted to address a problem with rebate collection on drugs administered in physicians' offices – not hospital outpatient clinics and departments.**

In the proposed rule, CMS seeks to give a much broader application to physician-administered drugs. By including all covered outpatient drugs that “are typically furnished incident to a

physician's service," the agency expands the scope of Section 6002 well beyond the problem it was designed to address. Precise congressional impetus for enactment of Section 6002 appears to be the April 2004 report "Medicaid Rebates for Physician-administered Drugs" from the Department of Health and Human Services Office of the Inspector General (OIG). In that report, the OIG projected that the states were losing millions of dollars in Medicaid rebate payments due to their failure to collect rebates on physician-administered drugs. The OIG report expressly defines the physician-administered drugs of concern as "drugs that a medical professional administers to a patient in a physician's office."

In the proposed rule, CMS acknowledges the relationship between this OIG report and enactment of Section 6002. The preamble makes numerous references to the "physician-administered drugs" covered by the OIG report, including a statement that current estimates of Medicaid savings from implementing Section 6002 are based on the 2004 OIG report. CMS' discussion appears to directly equate the physician-administered drugs that were the subject of the OIG report with those that are subject to Section 6002 and its proposed regulation.

Thus, the intent of Congress in enacting Section 6002 will be faithfully executed, and CMS' projected savings fully realized, if the proposed new NDC submission and collection requirements are construed as applicable only to drugs administered in physician's offices, and inapplicable to drugs administered in hospital outpatient clinics and departments.

**Section 6002 does not affect the existing rebate exemption for drugs administered to patients in hospital outpatient clinics and departments.**

Nothing in Section 6002 casts doubt on the continuing existence of the Medicaid statute's pre-existing exemption from drug rebate requirements for outpatient drugs established by Section 1927(j) of the *Social Security Act*. Section 6002's language is entirely silent as to any legislative intent to repeal or amend this pre-existing exemption, which expressly identifies outpatient drugs dispensed through hospital outpatient clinics and departments as not subject to the Medicaid drug rebate requirements.

The DRA Conference Report explicitly states that hospital outpatient clinic and managed care drugs described in Section 1927(j) are exempt from rebate requirements, and that the Section 6002 data collection requirements are intended to pertain only to physician-administered drugs for which there is no statutory exemption from rebate requirements (See H.R. Rept. No. 109-362 accompanying S.1932, December 19, 2005) Although the conference report does not directly cite Section 1927(j) *per se*, it expressly acknowledges the existence of exemptions from rebate requirements for outpatient prescription drugs using terms that unmistakably mirror the descriptions of managed care drugs in Section 1927(j)(1) and hospital drugs in Section 1927(j)(2).

Notwithstanding this clear legislative intent, CMS' proposed rule to implement Section 6002 makes no mention of the statutory exemptions from rebate requirements for either hospital

outpatient clinic drugs or outpatient drugs dispensed by managed care organizations. The fact that neither exemption is addressed in the proposed rule is, at best, confusing, but clearly evidence that CMS overlooked the entire matter of these statutorily exempt physician-administered drugs in construing how Section 6002 should be properly applied, as opposed to having simply construed Section 1927(j)(2) to have severely limited application to hospital outpatient clinic drugs.

It is clear that the physician-administered drug provision enacted by Section 6002 can only be read to impose a data collection requirement with respect to drugs that are not within the Section 1927(j) (2) exemption. Because the subsection (j) remains unchanged in the Medicaid rebate law, CMS cannot ignore the statutory exemption. The agency must continue to give subsection (j) the same meaning it had prior to the enactment of the DRA as the agency applies Section 6002. In doing so, CMS is compelled to draw meaning from Section 1927(j) (2) in a concrete way by referring to drugs dispensed or administered in an actual hospital setting.

Section 1927(j)(2) specifically exempts from the rebate requirements outpatient drugs that are administered in a "hospital ... that dispenses covered outpatient drugs using formulary systems, and bills [the Medicaid State Plan in the relevant state] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan)." This section cannot plausibly be construed as a reference to hospitals participating in the 340B federal drug discount program because the 340B program did not exist at the time Section 1927(j) was enacted.

On the other hand, drugs administered by medical professionals to patients on an outpatient basis in hospital clinics and departments generally have not been subject to Medicaid rebate collections, and fall squarely within the (j)(2) exemption, as properly construed. Drugs administered in the hospital outpatient clinic setting are dispensed almost always within a formulary system – thus meeting the first statutory criterion for inclusion in the (j)(2) exemption. Covered outpatient drugs administered in hospital clinic settings also are billed to Medicaid in a manner that meets the description of the second (j)(2) criterion, namely that the hospital "bills the [Medicaid State Plan] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the state plan)." Most, if not all, drugs administered to Medicaid-eligible patients in hospital outpatient clinics and departments fall within the (j)(2) exemption from rebates, and accordingly must be excluded from the physician-administered drugs to which Section 6002 applies.

#### **ADMINISTRATIVE BURDEN FOR HOSPITALS**

On January 1, 2007, the State of Kansas Medicaid Agency moved forward with implementing this new NDC reporting requirement. Hospitals have been instructed to bill outpatient drugs using the drug manufacturer's 11-digit NDC number. The KHA is concerned because these instructions fail to recognize the significant difficulty, burden and cost imposed upon the hospital

community in order to meet these new billing requirements. Most, if not all, hospital patient accounting systems are not designed to handle the routine reporting of a drug manufacturer's NDC. Today, hospital patient accounting systems rely on the Healthcare Common Procedure Coding System (HCPCS), in particular, the HCPCS J-codes to report a particular drug or biologic rendered to a patient. The J-code is not exclusive to a particular drug manufacturer but rather used to describe the general ingredient and dosage of a drug. Patient accounting systems can easily report HCPCS codes, but not the NDC.

To be able to report the NDC, hospitals must make major revisions to their charge description master (CDM), including significant increases to the CDM in order to include multiple manufacturers of a particular type or category of drug. Additionally, any manufacturer changes in the packaging, dosage and/or ingredients would require adding another NDC to the CDM and thereby increase the frequency of updating the CDM.

It should be noted that the language in the DRA conference report specifically indicates that the state Medicaid programs must "provide for the collection and submission of utilization and coding information for each Medicaid multiple source drug that is physician administered." The DRA further states that the "reporting would include J-codes and NDCs." As such, the KHA believes that state Medicaid agencies must provide for the collection process and bear the cost for hospitals to meet these new NDC reporting requirements. State Medicaid programs should pay hospitals to handle the system changes and new work routines required to collect and submit this coding information.

Preliminary estimates, which focus on rudimentary changes to hospital systems, indicate that it will take hundreds of work hours to design, build and test a short-term work around. Even with these changes, there are no absolute assurances that the NDC indicated on the claim reflects the manufacturer of the drug that was given to the patient. Many hospital pharmacy acquisition systems have limited record keeping ability and can assign only a primary NDC for a particular drug. The primary NDC reflects the manufacturer of a particular type of drug. When a drug needs to be replenished, the pharmacy goes to the primary manufacturer; however, often the primary manufacturer cannot supply or meet the hospital's need. In such instances, the hospital pharmacy seeks a secondary drug from another manufacturer with a different NDC. This is a common occurrence. Consequently, the hospital pharmacy's record keeping systems will need the ability to include multiple secondary sources for similar drugs. These changes also require massive system modifications and additional work routines.

During the past several years many hospitals have introduced new automated drug dispensing systems in an effort to reduce medication errors. Many of these systems also would require costly modifications. For example, these drug dispensing systems have bins for each specific drug based on ingredient and dosage – not on manufacturer NDC. There also is a human cost since hospitals that are interested in acquiring such systems to reduce medication errors would have to postpone their acquisition until the vendors make all of the system modifications.

Leslie Norwalk  
February 20, 2007  
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We urge CMS to revise its interpretation of Section 6002 of the DRA and not require the reporting of physician-administered drugs to hospital outpatient or clinic settings. We are willing to work with you to ensure the appropriate implementation of Section 6002 of the DRA. If you have questions about our comments, please contact me or Tish Hollingsworth, Director of Reimbursement at 785-276-3132 or [thollingsworth@kha-net.org](mailto:thollingsworth@kha-net.org).

Sincerely,

Fred J. Lucky  
Senior Vice President  
Kansas Hospital Association

CMS-2238-P-1381

**Submitter :** Ms. Michelle Steinberg

**Date:** 02/20/2007

**Organization :** Planned Parenthood of Central and Northern Arizona

**Category :** Other Health Care Provider

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-2238-P-1381-Attach-1.DOC

FROM PLANNED PARENTHOOD OF CENTRAL AND NORTHERN ARIZONA

February 20, 2007

Leslie V. Norwalk, Esq.  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Attention: CMS-2238-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

Planned Parenthood of Central and Northern Arizona is the largest provider of reproductive health care and education in Arizona, which operates 17 non-profit outpatient clinics in five counties. We provide health care to over 25,000 uninsured and underinsured women each year. PPCNA serves a total of over 60,000 patients each year, many of whom could not otherwise afford the health services—particularly oral contraceptives—that we provide. Planned Parenthood of Central and Northern Arizona is committed to providing low cost reproductive health care services to patients who need them most.

For over 69 years, PPCNA

- Has been providing quality family planning services to the people of Metropolitan Phoenix, Flagstaff, Prescott, Globe, Goodyear, and Yuma.
- PPCNA's 17 Health Centers provide a wide range of reproductive health care services to more than 60,000 individuals annually.
- Has provided services that prevent unintended pregnancies, reduce the need for abortion, lower rates of sexually transmitted diseases (STDs), including HIV, detect breast and cervical cancer at its earliest stages, and improve women's health. Our ability to obtain drugs at nominal prices allow us to provide oral contraceptive pills at prices far below retail prices to populations of women who otherwise couldn't afford these pills.

In 2006, we served 21,869 women at or below 100% FPL, 1,242 between 101 - 150% FPL, 546 between 151 - 200% FPL, and 1,101 201% FPL or greater. Another 33,085 women served, were at an unknown income level, many of whom were self pay clients.

PPCNA has been able to serve women in need of low-cost reproductive health care services because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. The impact on the low-income, uninsured, and underinsured patients we serve will be significantly; negatively impacted if we can no longer purchase drugs at these nominal prices and therefore low-income, uninsured, and underinsured

women will no longer have access to these oral contraceptives. This could impact more than 30,000 patients. Without these steeply discounted drugs, we will no longer be able to provide the low-cost outlet for poor women that they so desperately need, and that we very much want to continue to provide

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Many of PPCNA's Planned Parenthood sister health centers across the country are Title X clinics, and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. Some of the PPCNA centers, however, are not federally funded. Therefore, they do not qualify as a 340B covered entity.

At the same time, PPCNA serves as a key safety net provider to our communities. Our ability to continue to do so rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we were deeply disappointed when CMS did not define "safety net provider" or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule. Unfortunately, like many other small safety net providers, we do not qualify for the three categories listed above.

We sincerely hope that the Centers for Medicare and Medicaid Services (CMS) will reconsider and exercise its authority to name "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. PPCNA is clearly a safety net provider and we strongly urge CMS to include in its definition of safety net providers nonprofit, outpatient clinics like ours.

Respectfully submitted by,

Michelle Steinberg  
Planned Parenthood of Central and Northern Arizona  
Phoenix, Arizona

**Submitter :** Ms. Jacqueline Payne

**Date:** 02/20/2007

**Organization :** Planned Parenthood Federation of America

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1382-Attach-1.PDF

CMS-2238-P-1382-Attach-2.PDF

# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

January 31, 2007

## Via Electronic Transmission

Leslie V. Norwalk, Esq.  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Acting Administrator Norwalk:

The United States Senate Committee on Finance (Committee) has exclusive jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to oversee the proper administration of these programs, including reviewing pricing practices that could impact the cost to taxpayers of purchasing prescription drugs. In recent years, the cost to Medicaid of purchasing prescription drugs has grown faster than any other single area of the program. As a result of the combination of increasing costs and tight fiscal constraints, some States have been forced to reduce prescription drug benefits. Considering that prescription drugs are such an integral part of quality health care, such reductions in benefits may be detrimental to the health of Medicaid beneficiaries.

During the 109<sup>th</sup> Congress, the Committee studied issues relating to the Medicare and Medicaid programs' coverage of prescription drug benefits, including the use of the nominal price exception (NPE/nominal pricing) under the Medicaid Drug Rebate Program.<sup>1</sup> We write to share our findings to assist you in the rulemaking process in which you are currently engaged.

In particular, the Committee was concerned about the consequences of nominal pricing when used as a marketing tool, including, but not limited to, driving up best price and lowering the amount of rebates manufacturers pay States for Medicaid drugs. Based on the Committee's review of nominal pricing, our Committee Staff crafted legislative provisions regarding the NPE in the Deficit Reduction Act of 2005 (DRA), which the President signed into law on February 8, 2006. Section 6001(d) of the DRA requires manufacturers to report information on sales at nominal prices to the Secretary of Health and Human Services (HHS). It also specifies the purchasers for which sales at nominal prices may be excluded from the calculation of best price. It limits the merely nominal exclusion to sales at nominal prices to the following: a covered entity described in section

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<sup>1</sup> Congress amended the Social Security Act by adding section 1927, which created the Medicaid Drug Rebate Program for outpatient pharmaceuticals, when it passed the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990).

340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR), a State-owned or operated nursing facility, and any other facility or entity that the Secretary determines is a safety net provider to which sales of drugs at a nominal price would be appropriate, based on certain factors such as type of facility or entity, services provided by the facility or entity, and patient population.

On December 16, 2006, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule seeking to implement the provisions of the DRA pertaining to prescription drugs under the Medicaid program. The proposed rule addressed the changes to the nominal price exception contained in section 6001(d) of the DRA, but failed to give the Secretary the full authority Congress intended. The proposed rule includes three of the four categories of purchasers for which manufacturers will continue to be able to exclude sales made at nominal prices from their best price calculations. CMS's elimination of the fourth category concerns us. The proposed rule also addresses a broad range of issues relating to the determination of average manufacturer price (AMP), determination of best price, treatment of authorized generics, and new manufacturer reporting requirements, among others. In particular, we noted that CMS raised concerns regarding the continued use of the NPE as a marketing tool:

CMS has concerns that despite the fact that the DRA limits the nominal price exclusion to specific entities, the nominal price exclusion will continue to be used as a marketing tool. Historically, patients frequently remain on the same drug regimen following discharge from a hospital. Physicians may be hesitant to switch a patient to a different brand and risk destabilizing the patient once discharged from the hospital. We believe that using nominal price for marketing is not within the spirit and letter of the law. We are considering crafting further guidance to address this issue. CMS invites comments from the public to assist us in ensuring that all aspects of this issue are fully considered.

Based on the Committee's review of how the pharmaceutical industry has used the NPE under the Medicaid Drug Rebate Program, we share CMS's concern that nominal pricing may continue to be used as a marketing tool. The purpose of this letter is to report to CMS the Committee's findings with respect to its review of nominal pricing.

In 2004, we sent letters to 19 pharmaceutical manufacturers requesting information and data to assess how frequently the NPE was used, in what contexts, and for what purposes. In addition, we sought to determine: (1) whether, and to what extent, the NPE is used to promote access to prescription drugs as intended by Congress; and (2) whether refinements should be made to the existing statutory language to ensure that the NPE is not used for purposes other than those intended. Our Committee Staff focused on the top twenty pharmaceutical manufacturers, based on U.S. sales in 2003.<sup>2</sup> Our Committee Staff also focused on data related to eight leading therapeutic drug classes by U.S. sales

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<sup>2</sup> [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_42720942\\_44304255,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_42720942_44304255,00.html) One of the top-twenty manufacturers was excluded because it did not manufacture a brand name drug.

in 2003.<sup>3</sup> The eight drug classes reviewed were: statins, proton pump inhibitors, anti-depressants, anti-psychotics, erythropoietins, seizure disorder drugs, calcium channel blockers, and anti-arthritis/non-steroidal anti-inflammatory drugs (NSAIDs).<sup>4</sup>

In 2005, we sent a second letter to the same 19 pharmaceutical manufacturers based on concerns that some manufacturers appeared to be applying the NPE more broadly than Congress originally intended. The second letter requested information to understand further how some manufacturers used the NPE and why some others were not using it. Some manufacturers were asked about their use of the NPE for periods of only one quarter. A number of manufacturers were asked why they did not utilize nominal pricing, whether the manufacturers' customer bases included charitable organizations, and whether other discounts or special pricing were offered to those customers. Finally, we sent a third letter to one manufacturer, after our Committee Staff determined that one manufacturer had used the NPE outside the timeframe of the Committee's inquiry. This third letter focused specifically on that manufacturer's past policies and practices with respect to the NPE. All manufacturers voluntarily complied with the Committee's requests for documents and information.

Our Committee Staff reviewed the manufacturers' responses, including information regarding written policies and procedures related to the NPE and sales information on specific drugs. After reviewing the first and second round of responses, our Committee Staff identified several specific practices and held meetings with the six manufacturers that engaged in one or more of those practices to learn more about them. The Committee Staff also contacted one manufacturer that did not engage in nominal pricing to learn more about why it had not used the NPE. During those conversations, our Committee Staff also solicited opinions from the manufacturers' representatives as to whether the NPE should be subject to legislative or administrative changes.

In addition to information gathered directly from the pharmaceutical manufacturers, our Committee Staff considered other relevant sources of information, including: reviewing various reports prepared by the Government Accountability Office (GAO) and the Office of Inspector General (OIG) at HHS related to prescription drug coverage under Medicaid; analyzing HHS regulations regarding the Medicaid Drug Rebate Program; and reviewing publicly available complaints and settlement agreements from lawsuits where the use of the nominal price exception was part of alleged misconduct by a number of pharmaceutical manufacturers. Our Committee Staff also held meetings with CMS, the Department of Veterans Affairs (VA), the HHS OIG, and the GAO to discuss the Medicaid Drug Rebate Program generally and the NPE specifically.

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<sup>3</sup> [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_42720942\\_44304299,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_42720942_44304299,00.html)

<sup>4</sup> Some manufacturers did not produce a drug in any of the eight classes, therefore specific drug information and data were not obtained from those manufacturers.

Our Committee Staff determined that the NPE was used primarily as a competitive or marketing tool among the pharmaceutical manufacturers surveyed and was not used primarily for charitable purposes as intended by Congress. Our Committee staff made eight observations based on the information submitted to and obtained by the Committee:

1. Most manufacturers surveyed used the NPE inconsistent with Congressional intent
2. Most manufacturers' policies did not reflect use of the NPE for charitable purposes
3. Most manufacturers used the NPE for products in the best-selling classes of drugs
4. Hospitals appeared to be the primary recipients of nominal pricing
5. Most manufacturers did not differentiate between for-profit and not-for-profit entities when offering nominal pricing
6. A charitable purpose was rarely a factor considered by manufacturers in deciding to offer nominal pricing
7. Manufacturers' nominal pricing agreements frequently included market share requirements
8. Manufacturers' overall use of the NPE appears to have declined from 2003 forward

The Committee's findings and observations are discussed below in more detail, preceded by a brief background regarding the rationale for and Congressional intent behind the NPE and its use for charitable purposes.

### **Nominal Pricing Background**

Congress included the NPE in the Medicaid reforms of OBRA 1990 to ensure that efforts to more closely align Medicaid's drug pricing with pricing for private purchasers did not threaten the steep discounts on pharmaceutical products offered to certain purchasers. Recognizing that charitable and other organizations that provide health care to populations with limited access to health care often receive special discount prices for pharmaceutical products, Congress wanted to encourage manufacturers to continue offering deep discounts to such purchasers. Specifically, by excluding nominal prices from a manufacturer's best price calculation, Congress, under the original law, intended to allow pharmaceutical manufacturers to continue offering discounts to charitable organizations without dramatically increasing the rebate due to states. If nominal prices were not excluded from a manufacturer's best price calculation, a manufacturer that offered discounts to charitable organizations greater than those offered to regular customers would have to remit to the State Medicaid program a rebate for the difference

between AMP and the deeply discounted price. Concerned that manufacturers might stop offering such discounts as a result, Congress saw the nominal pricing exception as a way to maintain the practice of deep discounts to charitable organizations while still attempting to more closely align Medicaid's drug pricing with pricing for private purchasers.

Legislative history provides some insight into the intended purpose of the NPE as originally crafted. In 1990, before Congress passed OBRA 1990, the then-Chairman of the Senate Special Committee on Aging prepared and submitted for publication in the Congressional Record a statement entitled "Analysis of Drug Manufacturer Medicaid Drug Discount Proposals and Necessary Elements of Medicaid Drug Price Negotiation Plan," which stated that under the Rebate Program, the "merely nominal" prices that were excluded from best price calculations were those "such as the sale of birth control pills for a penny a pack to Planned Parenthood." A report by the Senate Special Committee on Aging, entitled "Developments in Aging: 1990," echoed this explanation for the exception, stating that "Congress did not want to threaten" the dramatic discounts offered to "charitable organizations and clinics" by requiring manufacturers to calculate and remit rebates based on prices not calculated with the market or any profit motive in mind.<sup>5</sup> During Congressional deliberations on OBRA 1990, the Senate Committee on Finance refined this explanation of "nominal price" slightly by defining the prices offered to Planned Parenthood, for example, as "token" prices.

Our Committee Staff held discussions with CMS officials regarding the regulatory history of the NPE. CMS officials told our Committee Staff that the definition of nominal as less than ten percent of AMP was the product of negotiations involving pharmaceutical manufacturers, pharmacists and the States. Specifically, CMS officials stated that the charitable intent behind including the NPE in the original law was mentioned during those negotiations.

The Department of Veterans' Affairs (VA), a major purchaser of drugs, has defined nominal prices more narrowly than CMS and described the conditions under which it believes nominal pricing may be used. In 1996, the VA Office of General Counsel sent a letter to pharmaceutical manufacturers that included the following discussion of nominal pricing:

The "nominal" pricing exclusion in the Veterans Health Care Act of 1992, Section 603 (38 U.S.C. 8126) was not intended to protect incentive use schemes by eliminating from non-FAMP calculations all below-cost sales of a covered drug that result from customers' purchases of sizable quantities of packages at a standard commercial price. VA views "nominal" pricing as being pricing, usually below cost, designed to benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose.

In addition, in 2000, the VA proposed amending its Master Agreement with pharmaceutical manufacturers to define "nominal price" as "[a]ny price less than 10% of the non-FAMP in the previous quarter from a sale (usually below cost) designed to

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<sup>5</sup> S. Rep. No. 102-28(I) (Mar. 22, 1991).

benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose.<sup>6</sup> VA officials advised our Committee Staff that the proposed change to the Master Agreement was never adopted due to opposition from the pharmaceutical industry, however, the VA's interpretation of nominal pricing as stated in the 1996 letter has not changed.

Nonetheless, several manufacturers surveyed by the Committee asserted that the NPE in no way limits sales at nominal prices to not-for-profit or charitable organizations. Several manufacturers, including those who did not use the NPE, stated to the Committee that sales at nominal prices are defined mathematically and are not limited to certain charitable organizations. For example:

Company G: "... the Act does not restrict nominal pricing solely to not-for-profit entities . . . . "

Company J: "It is the company's understanding that, as currently defined by Congress, the Medicaid Rebate Agreement and CMS, a nominal price is determined mathematically as any price less than ten percent of the AMP in the same quarter for which the AMP is computed."

Company K: "[Company K] interpret[s] the phrase "nominal price," for purposes of the Medicaid program, to denote a quantitative test in accordance with Section I.(s) of the Medicaid rebate template issued by [CMS]."

It appears to us that manufacturers were on notice that the primary intent of the NPE was to benefit charitable organizations. We note that some manufacturers have been legally counseled against broadly interpreting the NPE. For instance, one major law firm in Washington advised its clients in a "Health Care Reimbursement Client Alert: Medicaid Rebate Program," with the following precautionary statement:

The exclusion of nominal prices from BP [best price] calculations was primarily intended to avoid a chilling effect on manufacturers' in-kind contributions to charitable programs. CMS has adopted a bright-line rule that a nominal price is any price lower than 10% of AMP for the quarter. . . . Clients should also be careful if relying on nominal price in ordinary commercial situations where the absence of a purchase requirement might be questioned, because the exclusion of nominal prices is likely to be interpreted narrowly by CMS and it could be an area of potential inquiry on audit.

It appears to us that language in the explanatory material submitted by the Committee during consideration of OBRA 1990 and the subsequent Senate Committee on Aging report support the rationale and Congress's intent to limit the use of the NPE to charitable purposes. Congress most certainly did not intend for manufacturers to use the NPE as a marketing tool. Recognizing that nominal price is not defined by statute and that the definition adopted by CMS did not limit its applicability to charitable organizations, Congress enacted the DRA provisions requiring manufacturers to report

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<sup>6</sup> The Committee does not have the original draft amended Master Agreement, but obtained this definition from the American Bar Association's response to the proposed amendments.

information on sales at nominal price to the Secretary and specifying the entities to which the nominal price exception applies.

### **Nominal Pricing Observations**

#### **1. Most Manufacturers Surveyed Used the NPE Inconsistent with Congressional Intent**

Based on the information provided to the Committee by the manufacturers surveyed, it appears the pharmaceutical industry's practice with respect to the NPE can be grouped into three general categories: 1) manufacturers that appeared not to use the NPE; 2) manufacturers that appeared to use the NPE consistent with Congressional intent; and 3) manufacturers that appeared to use the NPE inconsistent with Congressional intent. Four manufacturers fell into category 1, three fell into category 2, and the majority of the manufacturers—12 out of 19—fell into category 3.

Manufacturers J, L, O and R, reported that they did not use the NPE. Manufacturer R, however, stated that it “. . . may consider use of the NPE under circumstances where it is commercially useful to do so and where it can be offered for all sales of a particular product to the relevant customer or customers for a period of at least one full calendar year.” All 19 manufacturers reported having charitable organizations in their customer base and no manufacturers reported refraining from nominal pricing because it was ambiguous. Manufacturers L and R indicated that although they did not use the NPE, they provided their products for free through patient assistance programs and other organizations.

Manufacturers C, G, and M provided information to the Committee that appeared to demonstrate use of the NPE consistent with Congressional intent. Manufacturers C and G sold drugs at nominal prices exclusively to not-for-profit organizations and did not place any conditions on sales at nominal prices. These manufacturers did not make nominal prices available to any not-for-profit organizations and only a very limited number of drugs were made available at nominal prices. In addition, Manufacturer C only offered nominal pricing for a limited period and did not offer any of its drugs for sale at a nominal price at the time of the Committee's inquiry. Manufacturer M had a general policy not to offer its drugs for sale at nominal prices, but continued to offer a drug it acquired to a single not-for-profit organization pursuant to a pre-existing agreement.

Twelve manufacturers—A, B, D, E, F, H, I, K, N, Q, P, and S— provided information to the Committee that appeared to demonstrate use of the NPE inconsistent with Congressional intent. Information regarding use of the NPE inconsistent with Congressional intent is discussed more fully below.

#### **2. Most Manufacturers' Policies Did Not Reflect Use of the NPE for Charitable Purposes**

Not one of the 19 manufacturers surveyed had written policies or procedures that addressed use of the NPE; however, several manufacturers provided policies, operations

procedures, best price assumptions, or similar documents that explicitly defined nominal price and/or addressed the inclusion of nominally priced drugs in calculating best price. Most manufacturers provided a description of their nominal pricing policy, but this was typically limited to a description of how pricing practices/proposals/contracts are evaluated or a statement that the company does not routinely make sales involving the NPE. Most manufacturers' policies did not reflect an intent to use the NPE for charitable purposes. The policy descriptions provided by the manufacturers surveyed included the following statements:

"[Manufacturer Q] does not routinely make sales at nominal price, therefore we are not able to describe in detail the factors and circumstances which [Manufacturer Q] takes into account in determining whether sales of covered outpatient drugs should be made at prices that are considered to qualify for the nominal price exception. Instead, [Manufacturer Q] would review each transaction on a case-by case basis to ensure that the transaction met all legal requirements and that the transaction had a rational business purpose..."

"Contract Prices that are less than 10% of a quarter's Average Manufacturer Price ("AMP") are excluded from Best Price." [Manufacturer P]

"Some products in [Manufacturer P's] product line have generic alternatives, and [Manufacturer P] sometimes elects to lower prices to establish price parity with generic products. From time to time, this price matching may have resulted in a price that could be calculated as nominal according to the definition set forth in the statutes. [Manufacturer P] has generally applied the NPE to these prices."

"Specific pricing at ten percent of AMP or less is not offered as a condition of sale; however, when various discounts or other price concessions for a particular customer are aggregated, it may be that some portion of the total price reduction may be conditioned on the promise to purchase one or more additional drug products. We note that such offers are contemplated by and protected by elements of federal law, to the extent that certain conditions are met. "  
[Manufacturer F]

In addition, only two manufacturers—G and I—specifically described the types of entities eligible for the NPE and only Manufacturer I specifically indicated that its policy was to use the NPE for charitable purposes.

### 3. Most Manufacturers Used the NPE for Products in the Best-Selling Classes of Drugs

The Committee obtained information regarding 84 drugs that were offered at nominal prices by the manufacturers surveyed. Eighteen of these products were among the eight best-selling classes of drugs. Ten of the 15 manufacturers that offered nominal pricing offered at least one of these drugs at the NPE. Three manufacturers only offered nominal pricing for their products in the eight best-selling classes of drugs. Of at least 30 drugs still offered at nominal prices as of March 2005, four were in the eight-best selling classes.

Two of the three manufacturers that used the NPE consistent with Congressional intent offered nominal pricing on drugs from the eight best-selling drug classes. Manufacturer C offered nominal pricing on only one drug and, of the three drugs offered by Manufacturer G at nominal prices, two were in the eight best-selling classes.

#### 4. Hospitals Appeared to be the Primary Recipients of Nominal Pricing

Hospitals appeared to be the primary recipients of nominal prices offered by those manufacturers that used the NPE consistent with Congressional intent. For those manufacturers that provided nominal prices only to not-for-profit entities, the NPE was only available to select not-for-profit entities. Manufacturer C offered nominal pricing to disproportionate share hospitals (DSH) that were participating covered entities in the 340B program, acute care teaching hospitals, and Federal government facilities purchasing from the Federal Supply Schedule. Manufacturer G offered nominal pricing “only with respect to certain of its products and only for certain not-for-profit hospitals.”

Hospitals were also the primary recipient of nominal pricing offered by those manufacturers whose use of nominal pricing appeared inconsistent with Congressional intent. Of the 12 manufacturers that offered nominal pricing to both for-profit and not-for-profit customers, six manufacturers indicated that hospitals were their only, or main, recipients of nominal prices. Another three manufacturers indicated that HMOs were offered nominal pricing. Some manufacturers identified the types of hospitals that received nominal pricing, which included acute care hospitals, DSH hospitals, teaching hospitals, and public hospital systems. Other recipients of nominal pricing identified by the manufacturers surveyed included Public Health Service covered entities, entities that serve the uninsured and organizations that offer family planning services.

By making the NPE available almost exclusively to hospitals, it appears manufacturers may have encouraged use of their drugs to the exclusion of competing products. They may also have created a spillover effect whereby patients who received their drugs while in the hospital continued to use them after discharge. Based on the information provided by manufacturers, the Committee cannot conclude that the primary intent of those manufacturers offering nominal pricing to hospitals was to compete against other manufacturers’ products or create a spillover effect. However, other information obtained by the Committee suggests that the use of nominal pricing in hospitals may increase demand for a product outside the hospital setting.

For instance, comments submitted to the VA in response to its efforts to narrow the definition of nominal price acknowledge that market penetration was the primary goal of providing nominal pricing to hospitals. The American Bar Association and at least one law firm representing a manufacturer, wrote to the VA concerning the nominal price definition in VA’s 2000 draft Amended Master Agreement, and stated: “Nominal prices have historically been granted to entities that do not fit within the VA’s narrow definition. For example, a manufacturer may grant nominal prices to hospitals in order to penetrate an established market . . .”

#### 5. Most Manufacturers Did Not Differentiate Between For-Profit and Not-for-Profit Entities

Although many of the hospitals and other organizations that were offered nominal prices may have been not-for-profit companies, not one of the manufacturers surveyed indicated that this was the reason for offering nominal pricing. The Committee asked the 12 companies that appeared to use nominal pricing beyond Congressional intent to identify differences in the way they treated for-profit and not-for-profit customers with respect to determining eligibility for nominal pricing. One manufacturer did not address the question, and the remaining 11 manufacturers indicated that there was no difference in how for-profit and not-for-profit organizations were treated. The following are sample responses from a few of these manufacturers:

“Purchasers are not limited to non-profit entities.” (Manufacturer P)

“In offering nominal pricing, [Manufacturer A] does not distinguish between for-profit and not-for-profit entities, consistent with the Medicaid rebate statute and the Medicaid rebate agreement.”

“[Manufacturer B] has not made distinctions between for-profit and not-for-profit hospitals when determining eligibility for nominal prices.”

#### 6. A Charitable Purpose Was Rarely a Factor When Offering Nominal Pricing

The Committee asked manufacturers to describe the factors and circumstances taken into account when determining whether sales of covered outpatient drugs should be made at nominal prices. Only one of the 15 manufacturers that reported using the NPE indicated that the existence of a charitable purpose was a factor considered when offering nominal pricing, while most manufacturers that reportedly used the NPE indicated that competitive market factors were taken into account when offering nominal pricing. Four manufacturers did not indicate to the Committee the factors and circumstances they took into account when offering nominal prices. One manufacturer reported that it used nominal pricing on a case-by-case basis when all legal requirements were met and a rational business purpose existed. Seven manufacturers listed a variety of factors, including: the business or competitive environment for a product; the degree of formulary control exercised by eligible customers; potential to increase patient access to the product; health outcomes information; and patient population, affordability and public policy considerations.

The following statements were made by manufacturers that indicated factors other than a charitable purpose, such as competitive marketing, when determining whether sales of covered outpatient drugs should be made at prices that are considered to fall within the NPE:

“[Manufacturer I] may offer Nominal Pricing on Multiple Source Drugs (i) to meet generic pricing on that same drug or (ii) to government entities and to not-for-profit institutions for charitable purposes.”

“... [Manufacturer P] sometimes elects to lower prices to establish price parity with generic alternatives to its products. From time to time, this pricing parity may have resulted in a price that could be calculated as nominal according to the

definition set forth in the Medicaid Rebate Agreement, and in such instances, [Manufacturer P] has applied the NPE to these prices.”

“[Manufacturer E was presented with credible evidence of] a price offer from a generic manufacturer that was nominal relative to the Company’s pricing structure for [drug]. The Company exercised its right of first refusal and entered into a contract to sell [drug] to [customer] at the low price, hoping to maintain brand loyalty through [customer’s] significant presence in the market.”

“Again, the determinative criteria were the competitive product pricing and the degree of formulary control involved.” (Manufacturer S)

“[Manufacturer K] consider[s] the market for the product (e.g., sites of demand, training medical practitioners, ability to influence prescriber or patient behavior, or formulary position), the nature of the customer, and the competitive environment (existence of generic or lower cost competition).”

“When determining whether and to whom sales of covered outpatient drugs should be made at nominal prices, as that term is defined in the rebate statute and rebate agreement, [Manufacturer A] takes into account the relevant customer(s) and the relevant economic and market conditions for sale of that particular product. For example, [Manufacturer A] will consider the overall pricing strategy for the product, the performance and pricing of competitive products, other discounts offered on the product, the type of customer, the potential to increase patient access to the product, and the effect of any discounts (nominal or otherwise) on net sales.”

“The existence of alternative products has generally been a factor in [Manufacturer N’s] contracts with nominal pricing in that [Manufacturer N] typically entered into those contracts at or near the time of patent expiration for certain products in order to try to retain sales in the face of competition from generic alternatives. While far less common, [Manufacturer N] has also from time to time entered into nominal pricing arrangements for certain products not facing generic competition in situations involving alternative products, such as situations involving nominal pricing from a competitive branded product.”

[Manufacturer H] takes a number of factors into consideration in developing pricing and contracting strategies, including any decisions about whether nominal pricing would be included in our strategies. Those factors include, among others, the business environment for a specific product, the number of competing products, health outcomes information, patient population, competitor pricing, affordability, and public policy considerations.

## **7. Nominal Pricing Agreements Frequently Included Market Share Requirements**

A majority of the 15 manufacturers that reported using nominal pricing placed conditions or limits on the offer of nominal pricing. The Committee asked manufacturers what types of contractual arrangements govern their company’s drug sales that fall under the NPE and specifically mentioned market share requirements and single quarter nominal pricing. Three manufacturers—F, G, and Q—did not provide information on the contractual terms associated with nominal pricing. Another three manufacturers—C, E, and M—indicated that there are no conditions attached to their offers of nominal pricing,

and one manufacturer—B—stated that, except for nominal price contracts with DSH hospitals, contracts for sales at nominal prices generally included a market share requirement. The remaining eight manufacturers—A, D, H, I, K, N, P, and S—all indicated that contracts for sales at nominal prices involved one or more of the following requirements or arrangements: market share requirements, volume requirements, nominal prices offered only for a single quarter of the year, formulary placement requirements, and unrestricted access requirements. Examples of manufacturer’s statements about these terms follow:

“Contracts offering Nominal Pricing may include a market share percentage provision.” (Manufacturer I)

“Generally, [Manufacturer A] pricing to institutional customers, including hospitals, conditions discounts on various factors such as agreements to make products available to patients on a less restrictive basis than would otherwise be the case and market share performance criteria.”

“Market share requirements may or may not be the basis for some of a series of discounts or other price concessions that may result in NPE pricing.”  
(Manufacturer F)

“A market share percentage is included in [Manufacturer B’s] contracts with hospitals as a requirement for eligibility for nominal pricing.”

“Certain historical contracts that included nominally priced products required formulary access for the nominally priced product, and/or for some or all of the other products in the contract.” (Manufacturer N)

“Certain historical contracts that included nominally priced products may have required, in addition to formulary access or availability, the customer to make a greater commitment to using the nominally priced and/or certain other products in the contract by granting them ‘preferred’ or ‘exclusive’ positioning.”  
(Manufacturer N)

All of these conditions or terms appear designed to increase the use of the product being offered at a nominal price. The Committee believes that the inclusion of such terms in nominal pricing contracts signals that the primary intent of the nominal price offer was to increase market share, and was therefore inconsistent with Congressional intent.

#### Use of the NPE May Be Declining

As of March 2005, most of the manufacturers that reported using the NPE indicated that they had reduced their use, stopped using it, or planned to stop using it once existing NPE contracts expired. While most of the practices uncovered would not be permitted under the DRA, only two manufacturers did not indicate an intention to eliminate or limit use of the NPE. Five manufacturers no longer used the NPE at all, and eight manufacturers had reduced or limited their use of the NPE. One manufacturer explained that it was reducing use of the NPE because it originally used nominal pricing only in an effort to meet price competition from a competitor that was offering its

products at nominal price. Two manufacturers explained their decision to stop using nominal pricing as follows:

“[Manufacturer N] discontinued its nominal pricing practices after concluding that the technical and administrative complexity and cost needed to sustain the nominal pricing programs outweighed the limited commercial benefits of preserving such programs.”

“[Manufacturer S] evaluated the commercial results of each of its nominal price contracts and determined that these discounts were not commercially justified.”

As with some manufacturers’ rationale for offering nominal pricing, the rationale offered for discontinuing nominal pricing also appear related to pricing or business strategies.

We respectfully submit these findings and observations to assist CMS as it considers crafting further guidance to address the use of the nominal price exception as a marketing tool. In addition, we respectfully request that CMS keep the Committee fully informed regarding the development of additional guidance and/or regulations pertaining to the NPE. Finally, please let us know whether or not further statutory changes may be necessary to address our shared concern regarding the NPE.

We look forward to hearing from you regarding the contents of this letter by February 15, 2007. In particular, we are interested in your addressing the reason why, in the proposed rule, the Secretary was not given the full authority Congress intended. Any questions or concerns should be directed to our Committee Staff,

*All correspondence should be sent via facsimile to (202) 228-2316 (majority) and (202) 228-2131 (minority), and original by U.S. mail. All formal correspondence should be sent via electronic transmission in PDF format to or via facsimile to (202) 228-2131 and original by U.S. mail.*

Sincerely,



Max Baucus  
Chairman



Charles E. Grassley  
Ranking Member



# Planned Parenthood

Federation of America, Inc.

1780 Massachusetts Avenue, NW, Washington, DC 20036  
 Phone 202.973.4800 • Fax 202.296.3242  
 www.plannedparenthood.org

February 20, 2007

## AND ELECTRONIC SUBMISSION

Leslie V. Norwalk, Esq.  
 Acting Administrator  
 Centers for Medicare and Medicaid Services  
 Department of Health and Human Services  
 Hubert H. Humphrey Building, Room 445-G  
 200 Independence Avenue, SW  
 Washington, D.C. 20201

**RE: Comments on the Medicaid Drug Program Proposed Rule;  
 II. Exclusion from Best Price of Certain Sales at a Nominal  
 Price – Section 447.508; File Code CMS-2238-P**

Dear Ms. Norwalk:

The Planned Parenthood Federation of America (“Planned Parenthood”) is pleased to submit these comments on the Medicaid Drug Program Proposed Rule (“Proposed Rule”), published December 22, 2006 at 71 FR 77174 *et seq.* Specifically, Planned Parenthood submits these comments regarding the Proposed Rule’s treatment of §6001(d)(2) of the Deficit Reduction Act of 2005 (“DRA”) regarding nominal sales.

Planned Parenthood is the nation's leading nonprofit reproductive health care provider to the uninsured and underinsured. With 117 affiliates operating more than 860 health centers nationwide, nearly five million women, men, and teens rely on Planned Parenthood each year for essential reproductive health care services. Planned Parenthood is committed to providing these services regardless of the patient’s ability to pay. Central to Planned Parenthood’s services is the provision of oral contraceptive medications. Millions of women receive these vital drugs from Planned Parenthood clinics each year for free or at prices below the market rate.

As written, the Proposed Rule is seriously deficient and clearly not in line with Congressional intent in that it omits many Planned Parenthood clinics from eligibility to purchase drugs at best price ineligible nominal prices (hereafter simply “nominal prices”). Without access to nominally priced oral contraceptive medications, many of these nonprofit safety net providers will literally be forced to shut their doors: they have been informed by manufacturers that as of this past January 1<sup>st</sup>, they will have to pay list price for these drugs. We strongly urge the Center for Medicare and Medicaid Services (“CMS”) to abide by Congressional intent and create a definition of safety net provider that includes all Planned Parenthood affiliates so that they may continue to serve uninsured and underinsured patients across the nation.

## Background

When the Medicaid Drug Rebate Program was created in 1990, Congress took special care to protect Planned Parenthood and similarly situated health care providers from sharp price increases due to the establishment of best price. Manufacturers were permitted to exclude from best price those sales that were made at “merely nominal prices.” A “nominal price” was determined to be any price less than ten percent of the current quarter’s Average Manufacturer Price. The effect of this nominal pricing exception (“NPE”) to the best price rules was to encourage drug manufacturers to continue to offer steep discounts to safety net providers like Planned Parenthood.

In fact, the NPE was created by Congress with Planned Parenthood specifically in mind. The legislative history of the NPE contains multiple direct references to Planned Parenthood. For example, during the debate on OBRA '90, Arkansas Senator David Pryor included in the Congressional Record a statement confirming that safeguarding “the sale of penny a pack birth control pills to Planned Parenthood” was good public policy and that such sales should be excluded from best price. 135 Cong. Rec. S12954-01 (Sept. 12, 1990). A later report by the Senate Special Committee on Aging reiterated this sentiment, stating “Congress did not want [by establishing the best price rules] to threaten the prices that charitable organizations and clinics such as Planned Parenthood pay for drugs...” S. Rep. No. 102-28(I) at 254 (Mar. 22, 1991). The Senate Finance Committee “refined [the] explanation of ‘nominal price’ slightly by defining the prices offered to Planned Parenthood, for example, as ‘token prices.’” See Letter from the U.S. Senate Committee on Finance to Leslie V. Norwalk, January 31, 2007 at 5, attached (“Finance Letter”).

Over time, certain members of Congress became concerned that the NPE was being abused by some drug manufacturers. These companies allegedly offered nominal prices not to support the work of charitable organizations like Planned Parenthood, but to market their goods to the detriment of the federal healthcare system. See Finance Letter at 4-5.

In response, the Finance Committee crafted §6001(d) of the DRA, which limits to four the number of categories of purchasers that are eligible for nominal prices. See Finance Letter at 1. Those categories are: (I) 340B covered entities, (II) intermediate care facilities for the mentally retarded, (III) state owned or operated nursing facilities, and (IV) any other facility or entity that the Secretary of HHS determines is a safety net provider to which sales of drugs at a nominal price would be appropriate (based on the type of entity, the services provided, patient population and proximity to other safety net providers). DRA §6001(d)(2) *amending* 42 U.S.C. §1396r-8(c)(1).

The Proposed Rule accepts the first three categories of NPE eligible entities, but fails to define or apply the fourth.<sup>1</sup> CMS claims that the DRA granted it the discretion to include or not to include safety net providers in the NPE. The Proposed Rule cites three reasons for CMS’s decision not to permit safety net providers to purchase drugs at nominal prices: first, because the

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<sup>1</sup> Section 6001(d) is addressed in the preamble at 71 FR 77184-85, and in the proposed regulations at §447.508.

other three categories “are sufficiently inclusive and capture the appropriate safety net providers,” second, because “adding other entities or facilities would have an undesirable effect on the best price by expanding the entities for which manufacturers can receive the best price exclusion ... and lowering manufacturer rebates to the Medicaid Program,” and third, because inclusion of other safety net providers may heighten the risk that manufacturers would use the NPE impermissibly as a marketing tool. *See Proposed Rule at 77185.*

Planned Parenthood strongly disagrees with the Proposed Rule’s interpretation of §6001(d). As detailed below, Congress clearly intended that CMS define and apply the safety net provider category. The justifications put forward by CMS for its refusal to do so are insufficient and not supported by fact. Meanwhile, non-340B safety net providers like many of Planned Parenthood’s affiliates and their multitude of needy patients have been placed at great risk. CMS must act expeditiously to avert a crisis in the nation’s reproductive health services network.

#### CMS Was Required by Congress to Define and Apply the Safety Net Provider Category

Congress intended that CMS establish a definition of “safety net provider” and permit such appropriate entities that do not fall into the other three categories to also purchase drugs at nominal prices. That CMS failed to do so is an abdication of its responsibility to Congress and to the hundreds of thousands of patients nationwide who will be harmed as a result.

As the strongly worded letter from the Chairman and Ranking Member of the Senate Finance Committee makes very clear, Congress intended that all four categories of entities be NPE eligible. The January 31, 2007 letter expressed its disappointment in the Proposed Rule’s failure to do so:

The proposed rule addressed the changes to the nominal price exception contained in section 6001(d) of the DRA, but failed to give the Secretary the full authority Congress intended. The proposed rule includes three of the four categories of purchasers for which manufacturers will continue to be able to exclude sales made at nominal prices from their best price calculations.

*CMS’s elimination of the fourth category concerns us.*

Finance Letter at 2 (emphasis added). The letter concludes with the Finance Committee’s desire to hear from CMS specifically on this issue: “In particular, we are interested in your addressing the reason why, in the proposed rule, the Secretary was not given the full authority Congress intended.” *Id.* at 13. This bipartisan expression of concern, from the very committee that drafted §6001(d), *id.* at 1, is strong evidence that the Proposed Rule errs in failing to define and apply the safety net provider category.

The language of the DRA itself also reflects Congressional intent that CMS make other safety net providers NPE eligible. The clear implication of permitting 340B covered entities *and* other safety net providers to utilize the NPE is that Congress did not mean to exclude safety net

providers merely on the basis of their funding stream<sup>2</sup>. Where two nonprofit entities perform the same healthcare function for similarly vulnerable populations, but one is a 340B covered entity and the other is not, it stands to reason that Congress intended them both to have access to the NPE. It is contrary to public policy to deny access to deeply discounted drugs to safety net providers -- such as non-340B Planned Parenthood affiliates -- who serve disproportionately poor populations *without* the benefit of federal funds.<sup>3</sup>

Nothing in the DRA gives the Secretary the authority to refuse to define safety net provider in the first instance. Rather, the Secretary's discretion extends only so far as to determine the appropriate definition. Section 6001(d) does not give the Secretary the authority to determine whether or not to define safety net provider, but only discretion in the creation and application of that definition.

Moreover, the fact that Congress drafted and included in the statute four factors for the Secretary to consider in crafting the definition of safety net provider suggests that the creation of such a definition was intended.

Planned Parenthood feels very strongly that CMS must, in its final rule, address this failure to abide by Congressional intent and propose a definition of safety net provider as required in §6001(d)(2).

#### The Reasons Given by CMS for Not Defining Safety Net Provider are Unpersuasive

Even if CMS had the authority to decline to define safety net provider -- and we do not believe that it did -- the reasons proffered by CMS in the Proposed Rule for doing so are insufficient and unpersuasive.

First, it is simply not true that the first three categories of providers "are sufficiently inclusive and capture the appropriate safety net providers." Proposed Rule at 77185. Despite the Proposed Rule's unsupported assertion to the contrary, there are a great many safety net providers that should be eligible for nominal pricing (and that have historically relied on nominal pricing to fulfill their charitable purposes) that are not captured by the other three categories. Planned Parenthood affiliates and clinics are an excellent example. The majority of Planned Parenthood health centers are 340B covered entities, and may continue to purchase nominally priced drugs under §6001(d)'s first category. Many Planned Parenthood affiliates and health centers are *not* 340B covered entities, however.<sup>4</sup> They receive no federal funds,<sup>5</sup> yet serve their communities' neediest patients by offering access to services regardless of the patients' ability to pay. There are 232 of these non-340B Planned Parenthood facilities in 32 states, serving

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<sup>2</sup> Note that "funding stream" is not one of the four factors for consideration in defining "safety net provider."

<sup>3</sup> Several non-340B Planned Parenthood entities may receive small federal grants.

<sup>4</sup> None are intermediate care facilities for the mentally retarded or state owned or operated nursing homes, the other two categories of NPE eligible entities.

<sup>5</sup> It is a cruel irony that those charitable health care providers that do not demand federal financial support would be excluded by federal regulation from access to deeply discounted drugs. Planned Parenthood cannot imagine that this was Congress' intent in passing §6001(d).

approximately 400,000 patients a year.<sup>6</sup> These worthy entities need CMS to define and apply the safety net provider definition to be eligible for nominal pricing, a critical factor in their continued operation. Please make no mistake, many of these health centers depend very heavily on nominally priced oral contraceptives, and will shut their doors in a matter of months if CMS does not reverse its position on this point.

Second, the Proposed Rule suggests that best prices will rise and state Medicaid programs will suffer lower rebates if other safety net providers are permitted to purchase at nominal prices. Proposed Rule at 77185. We do not believe this to be the case. There will be no effect on best price and Medicaid rebates of including non-340B safety net providers like Planned Parenthood affiliates in the NPE. Many of our affected affiliates have been told by drug manufacturers that in light of the Proposed Rule, they will have to pay list or market rates (WAC) for brand oral contraceptive drugs. These rates are significantly higher than nominal rates, and even higher than the price paid by large commercial for-profit entities. Manufacturers will simply not offer best price eligible pricing to nonprofit safety net providers -- they will raise (in this case dramatically) the prices offered to NPE ineligible entities to avoid the attendant Medicaid rebate liability. By including other safety net providers in the NPE, CMS will not forego new best prices. It follows that Medicaid rebates will not fall as a consequence. Expanding access to nominally priced drugs to non-340B safety net entities will not cost any federal, state or local government a dime -- the cost of these sales will be borne exclusively by drug manufacturers.

Third, as the Finance Committee inquiry demonstrates, and the Proposed Rule notes, the use of nominal pricing as a marketing tool is contrary to the intent of the NPE. The fact that such abuse has occurred in the past, however, when the NPE was open to any and all purchasers, does not suggest that expansion of the NPE to include non-340B safety net providers will perpetuate the abuse. It is telling that the Finance Committee itself, arguably the most active opponent of NPE abuse, urges CMS to define and apply the fourth category of NPE-eligible entities. Finance Letter at 2. There is risk of abuse in permitting any entity to purchase at nominal prices; Congress appears to believe, however, that the benefit of supporting the nation's network of safety net providers with low drug prices outweighs any such risk. Finally, there are better mechanisms than exclusion of non-340B safety net providers from NPE to prevent and detect abuse of the NPE.

#### CMS Should Define and Apply the Safety Net Provider Category

Planned Parenthood recognizes that crafting a workable definition of an NPE eligible safety net provider is a difficult task. Nevertheless, CMS is charged with this responsibility by the DRA, and cannot simply refuse, as it has done in the Proposed Rule.

The definition must be broad enough to cover all appropriate entities, while at the same time sufficiently detailed to avoid wholesale application and invite abuse. It must be mindful of

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<sup>6</sup> For example, Planned Parenthood serves 15% of all Colorado women in need of contraceptive services and supplies (which is roughly 33% of women in need of *publicly* funded contraceptive services and supplies).

those characteristics that make a health care provider a "safety net provider to which sales of [] drugs at a nominal price would be appropriate" based on the four factors. The integrity of the exception must be maintained by a definition that is respectful of the concerns raised by the Finance Committee regarding marketing abuse. Finally, the definition has to be specific enough to give clarity to drug manufacturers about which entities are and are not eligible for nominal pricing. Planned Parenthood appreciates this opportunity to suggest to CMS a framework for achieving all these ends.

In light of (1) specific Congressional intent from the early 1990's that nominal pricing be available to Planned Parenthood, *supra* at 2; (2) the Finance Committee's recent citation of that authority in its letter to CMS urging the definition and application of the fourth category, Finance Letter at 2; and (3) the harm that would be suffered by hundreds of thousands of patients at Planned Parenthood facilities around the country if the facilities are not returned to NPE eligibility, Planned Parenthood proposes that any definition be sure to include all Planned Parenthood affiliates and health centers. After all, family planning clinics such as those operated by Planned Parenthood affiliates are considered "core safety net providers" by the Institute of Medicine ("IOM") in its 2000 treatise on America's Health Care Safety Net. According to the IOM, "core safety net providers" are a key subset of the nation's broader health care safety net and play a critical role in providing services to the nation's most vulnerable populations. Such a definition, as detailed below, would also capture other similarly situated providers of safety net medical services.

A "safety net provider" eligible to purchase drugs at nominal prices under §6001(d) of the DRA should be a:

- (1) non-profit organization;
- (2) comprised of an outpatient clinic or several clinics;
- (3) that offers access to health care services to patients without regard to their ability to pay; and
- (4) a majority of whose patients are at 200% or less of the Federal Poverty Level.

We believe this definition to be both appropriate and workable. It squarely addresses three of the four statutory factors<sup>7</sup>: (I) the type of facility or entity (non-profit outpatient clinics that offer access to care without regard to the patient's ability to pay), (II) the services provided by the facility or entity (health care) and (III) the patient population served by the facility or entity (a majority at 200% or less of the FPL). It is designed with reference to the concerns of the Finance Committee with regard to NPE abuse in that it focuses on non-profit entities that provide services predominantly to the most needy, and it excludes hospitals which were noted to be the primary recipients of nominal pricing offered by manufacturers that abused the NPE. Finance Letter at 9-10. Furthermore, it provides a bright line for eligibility based on the

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<sup>7</sup> We do not believe the fourth factor, proximity to other safety net providers, is easily administrable and urge CMS to consider that factor only on a case-by-case basis for providers who do not otherwise meet the terms of the definition as established. For example, a *for-profit* facility 100 miles from any other NPE eligible facility may qualify to purchase drugs at nominal prices.

percentage of patients below 200% of the FPL.<sup>8</sup> A group of clinics that serve a patient population in which at least half are below 200% of FPL is clearly serving as a safety net provider of the type entitled to be eligible to purchase low cost drugs.

Planned Parenthood urges CMS to apply this definition retroactively to the beginning of 2007. Despite the Proposed Rule's non-final status, many manufacturers stopped offering nominally priced goods to non-340B safety net providers on January 1. Applying the definition retroactively would remove doubt as to the continued eligibility of the safety net providers, and assure drug manufacturers that any sales made to these entities prior to the issuance of the final rule would not set best price.

Finally, Planned Parenthood understands that central to any manufacturer's decision to offer nominally priced drugs is the question of NPE eligibility. If a manufacturer is not confident that an organization or entity is an NPE eligible entity, it will not offer that worthy safety net provider these deeply discounted drugs. The risk of unintentional best price exposure is simply too great. Therefore, Planned Parenthood urges CMS to present in its final rule a mechanism whereby drug manufacturers can be assured of a safety net provider's eligibility. This mechanism need not impose a great burden on CMS or the safety net providers to be effective. CMS could establish a simple self-certification regime for safety net providers<sup>9</sup>. When coupled with a regulatory presumption of eligibility in the absence of evidence to the contrary, we believe manufacturers would feel free to offer nominal prices to these certified providers. Alternatively, CMS could maintain a list of NPE eligible safety net providers based on individual requests for certification, as it maintains for State Pharmaceutical Assistance Programs in the best price context. Finally, CMS could maintain a registry of safety net providers eligible for NPE as the Office of Pharmacy Affairs does for 340B covered entities. Planned Parenthood simply wants to ensure that safety net providers will be eligible for the NPE, and that manufacturers will feel confident in offering it to them.

\* \* \* \* \*

In conclusion, Planned Parenthood vehemently urges CMS to reverse its position and define and apply the fourth category of NPE eligible entities, safety net providers, as required by Congress. The effect of the Proposed Rule would be to deny access to discounted drugs to many nonprofit outpatient clinics that do not enjoy federal funding, but nonetheless serve the public

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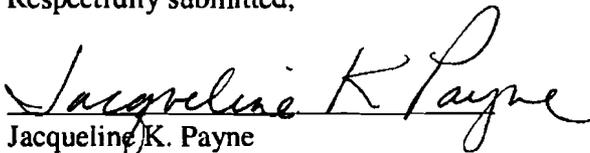
<sup>8</sup> 200% of FPL is an established and accepted measure of need within the federal healthcare system. Secretary Leavitt recently defended the Administration's budget estimates for the SCHIP program by saying that at the proposed level, it would cover all children at less than 200% of FPL. The HHS Agency for Healthcare Research & Quality ("AHRQ") Safety Net Monitoring Initiative uses 200% of FPL as one measure to monitor demand for safety net provider services. See [www.ahrq.gov/data/safetynet/databooks/chapter3.htm](http://www.ahrq.gov/data/safetynet/databooks/chapter3.htm). Federal community health centers, migrant health centers and Title X family planning clinics must offer free or discounted services to patients below 200% of FPL. *Measuring Poverty: A New Approach*, Constance Citro and Robert Michael, Ed., Panel on Poverty and Family Assistance: Concepts, Information Needs, and Measurement Methods, National Research Council, at pp. 437-439 (1995).

<sup>9</sup> Like that required in the ASP reporting context, or, as established by the DRA, the certification to be required of manufacturers when reporting AMP, best price and other data (including on nominal sales).

interest. Without access to nominally priced drugs, many of these entities will be forced to close their doors. Moreover, CMS should not ignore the plainly articulated intent of Congress to include Planned Parenthood, specifically, within the ambit of the NPE. The definition of safety net provider that we have proposed is both workable and appropriate. In conjunction with a mechanism for manufacturer assurance of eligibility, inclusion of non-340B safety net providers in the set of NPE-eligible entities will ensure that literally hundreds of thousands of needy patients each year can continue to receive the free or low cost reproductive health care services they require (as Congress intended), and on which scores of communities across America rely.

Thank you for this opportunity to comment on the nominal pricing provisions of the Proposed Rule. If Planned Parenthood can be of further assistance as CMS drafts and publishes its final rule, please do not hesitate to contact me directly at 202-973-4810.

Respectfully submitted,

A handwritten signature in cursive script that reads "Jacqueline K. Payne". The signature is written in black ink and is positioned above the printed name.

Jacqueline K. Payne  
Director of Government Relations  
Planned Parenthood Federation of America

Attachment

**Submitter :**

**Date: 02/20/2007**

**Organization :**

**Category : Pharmacist**

**Issue Areas/Comments**

**Background**

Background

q

**Collection of Information Requirements**

Collection of Information Requirements

q

**Provisions of the Proposed Regulations**

Provisions of the Proposed Regulations

q

**Regulatory Impact Analysis**

Regulatory Impact Analysis

q

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

**Submitter :** Ms. Jacqueline Payne  
**Organization :** Planned Parenthood Federation of America  
**Category :** Health Care Professional or Association

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1384-Attach-1.PDF



1780 Massachusetts Avenue, NW, Washington, DC 20036  
 Phone 202.973.4800 • Fax 202.296.3242  
 www.plannedparenthood.org

February 20, 2007

AND ELECTRONIC SUBMISSION

Leslie V. Norwalk, Esq.  
 Acting Administrator  
 Centers for Medicare and Medicaid Services  
 Department of Health and Human Services  
 Hubert H. Humphrey Building, Room 445-G  
 200 Independence Avenue, SW  
 Washington, D.C. 20201

**RE: Comments on the Medicaid Drug Program Proposed Rule;  
 II. Exclusion from Best Price of Certain Sales at a Nominal  
 Price – Section 447.508; File Code CMS-2238-P**

Dear Ms. Norwalk:

The Planned Parenthood Federation of America (“Planned Parenthood”) is pleased to submit these comments on the Medicaid Drug Program Proposed Rule (“Proposed Rule”), published December 22, 2006 at 71 FR 77174 *et seq.* Specifically, Planned Parenthood submits these comments regarding the Proposed Rule’s treatment of §6001(d)(2) of the Deficit Reduction Act of 2005 (“DRA”) regarding nominal sales.

Planned Parenthood is the nation’s leading nonprofit reproductive health care provider to the uninsured and underinsured. With 117 affiliates operating more than 860 health centers nationwide, nearly five million women, men, and teens rely on Planned Parenthood each year for essential reproductive health care services. Planned Parenthood is committed to providing these services regardless of the patient’s ability to pay. Central to Planned Parenthood’s services is the provision of oral contraceptive medications. Millions of women receive these vital drugs from Planned Parenthood clinics each year for free or at prices below the market rate.

As written, the Proposed Rule is seriously deficient and clearly not in line with Congressional intent in that it omits many Planned Parenthood clinics from eligibility to purchase drugs at best price ineligible nominal prices (hereafter simply “nominal prices”). Without access to nominally priced oral contraceptive medications, many of these nonprofit safety net providers will literally be forced to shut their doors: they have been informed by manufacturers that as of this past January 1<sup>st</sup>, they will have to pay list price for these drugs. We strongly urge the Center for Medicare and Medicaid Services (“CMS”) to abide by Congressional intent and create a definition of safety net provider that includes all Planned Parenthood affiliates so that they may continue to serve uninsured and underinsured patients across the nation.

## Background

When the Medicaid Drug Rebate Program was created in 1990, Congress took special care to protect Planned Parenthood and similarly situated health care providers from sharp price increases due to the establishment of best price. Manufacturers were permitted to exclude from best price those sales that were made at “merely nominal prices.” A “nominal price” was determined to be any price less than ten percent of the current quarter’s Average Manufacturer Price. The effect of this nominal pricing exception (“NPE”) to the best price rules was to encourage drug manufacturers to continue to offer steep discounts to safety net providers like Planned Parenthood.

In fact, the NPE was created by Congress with Planned Parenthood specifically in mind. The legislative history of the NPE contains multiple direct references to Planned Parenthood. For example, during the debate on OBRA '90, Arkansas Senator David Pryor included in the Congressional Record a statement confirming that safeguarding “the sale of penny a pack birth control pills to Planned Parenthood” was good public policy and that such sales should be excluded from best price. 135 Cong. Rec. S12954-01 (Sept. 12, 1990). A later report by the Senate Special Committee on Aging reiterated this sentiment, stating “Congress did not want [by establishing the best price rules] to threaten the prices that charitable organizations and clinics such as Planned Parenthood pay for drugs...” S. Rep. No. 102-28(I) at 254 (Mar. 22, 1991). The Senate Finance Committee “refined [the] explanation of ‘nominal price’ slightly by defining the prices offered to Planned Parenthood, for example, as ‘token prices.’” See Letter from the U.S. Senate Committee on Finance to Leslie V. Norwalk, January 31, 2007 at 5, attached (“Finance Letter”).

Over time, certain members of Congress became concerned that the NPE was being abused by some drug manufacturers. These companies allegedly offered nominal prices not to support the work of charitable organizations like Planned Parenthood, but to market their goods to the detriment of the federal healthcare system. See Finance Letter at 4-5.

In response, the Finance Committee crafted §6001(d) of the DRA, which limits to four the number of categories of purchasers that are eligible for nominal prices. See Finance Letter at 1. Those categories are: (I) 340B covered entities, (II) intermediate care facilities for the mentally retarded, (III) state owned or operated nursing facilities, and (IV) any other facility or entity that the Secretary of HHS determines is a safety net provider to which sales of drugs at a nominal price would be appropriate (based on the type of entity, the services provided, patient population and proximity to other safety net providers). DRA §6001(d)(2) *amending* 42 U.S.C. §1396r-8(c)(1).

The Proposed Rule accepts the first three categories of NPE eligible entities, but fails to define or apply the fourth.<sup>1</sup> CMS claims that the DRA granted it the discretion to include or not to include safety net providers in the NPE. The Proposed Rule cites three reasons for CMS’s decision not to permit safety net providers to purchase drugs at nominal prices: first, because the

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<sup>1</sup> Section 6001(d) is addressed in the preamble at 71 FR 77184-85, and in the proposed regulations at §447.508.

other three categories “are sufficiently inclusive and capture the appropriate safety net providers,” second, because “adding other entities or facilities would have an undesirable effect on the best price by expanding the entities for which manufacturers can receive the best price exclusion ... and lowering manufacturer rebates to the Medicaid Program,” and third, because inclusion of other safety net providers may heighten the risk that manufacturers would use the NPE impermissibly as a marketing tool. *See Proposed Rule at 77185.*

Planned Parenthood strongly disagrees with the Proposed Rule’s interpretation of §6001(d). As detailed below, Congress clearly intended that CMS define and apply the safety net provider category. The justifications put forward by CMS for its refusal to do so are insufficient and not supported by fact. Meanwhile, non-340B safety net providers like many of Planned Parenthood’s affiliates and their multitude of needy patients have been placed at great risk. CMS must act expeditiously to avert a crisis in the nation’s reproductive health services network.

#### CMS Was Required by Congress to Define and Apply the Safety Net Provider Category

Congress intended that CMS establish a definition of “safety net provider” and permit such appropriate entities that do not fall into the other three categories to also purchase drugs at nominal prices. That CMS failed to do so is an abdication of its responsibility to Congress and to the hundreds of thousands of patients nationwide who will be harmed as a result.

As the strongly worded letter from the Chairman and Ranking Member of the Senate Finance Committee makes very clear, Congress intended that all four categories of entities be NPE eligible. The January 31, 2007 letter expressed its disappointment in the Proposed Rule’s failure to do so:

The proposed rule addressed the changes to the nominal price exception contained in section 6001(d) of the DRA, but failed to give the Secretary the full authority Congress intended. The proposed rule includes three of the four categories of purchasers for which manufacturers will continue to be able to exclude sales made at nominal prices from their best price calculations.  
*CMS’s elimination of the fourth category concerns us.*

Finance Letter at 2 (emphasis added). The letter concludes with the Finance Committee’s desire to hear from CMS specifically on this issue: “In particular, we are interested in your addressing the reason why, in the proposed rule, the Secretary was not given the full authority Congress intended.” *Id.* at 13. This bipartisan expression of concern, from the very committee that drafted §6001(d), *id.* at 1, is strong evidence that the Proposed Rule errs in failing to define and apply the safety net provider category.

The language of the DRA itself also reflects Congressional intent that CMS make other safety net providers NPE eligible. The clear implication of permitting 340B covered entities *and* other safety net providers to utilize the NPE is that Congress did not mean to exclude safety net

providers merely on the basis of their funding stream<sup>2</sup>. Where two nonprofit entities perform the same healthcare function for similarly vulnerable populations, but one is a 340B covered entity and the other is not, it stands to reason that Congress intended them both to have access to the NPE. It is contrary to public policy to deny access to deeply discounted drugs to safety net providers -- such as non-340B Planned Parenthood affiliates -- who serve disproportionately poor populations *without* the benefit of federal funds.<sup>3</sup>

Nothing in the DRA gives the Secretary the authority to refuse to define safety net provider in the first instance. Rather, the Secretary's discretion extends only so far as to determine the appropriate definition. Section 6001(d) does not give the Secretary the authority to determine whether or not to define safety net provider, but only discretion in the creation and application of that definition.

Moreover, the fact that Congress drafted and included in the statute four factors for the Secretary to consider in crafting the definition of safety net provider suggests that the creation of such a definition was intended.

Planned Parenthood feels very strongly that CMS must, in its final rule, address this failure to abide by Congressional intent and propose a definition of safety net provider as required in §6001(d)(2).

#### The Reasons Given by CMS for Not Defining Safety Net Provider are Unpersuasive

Even if CMS had the authority to decline to define safety net provider -- and we do not believe that it did -- the reasons proffered by CMS in the Proposed Rule for doing so are insufficient and unpersuasive.

First, it is simply not true that the first three categories of providers "are sufficiently inclusive and capture the appropriate safety net providers." Proposed Rule at 77185. Despite the Proposed Rule's unsupported assertion to the contrary, there are a great many safety net providers that should be eligible for nominal pricing (and that have historically relied on nominal pricing to fulfill their charitable purposes) that are not captured by the other three categories. Planned Parenthood affiliates and clinics are an excellent example. The majority of Planned Parenthood health centers are 340B covered entities, and may continue to purchase nominally priced drugs under §6001(d)'s first category. Many Planned Parenthood affiliates and health centers are *not* 340B covered entities, however.<sup>4</sup> They receive no federal funds,<sup>5</sup> yet serve their communities' neediest patients by offering access to services regardless of the patients' ability to pay. There are 232 of these non-340B Planned Parenthood facilities in 32 states, serving

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<sup>2</sup> Note that "funding stream" is not one of the four factors for consideration in defining "safety net provider."

<sup>3</sup> Several non-340B Planned Parenthood entities may receive small federal grants.

<sup>4</sup> None are intermediate care facilities for the mentally retarded or state owned or operated nursing homes, the other two categories of NPE eligible entities.

<sup>5</sup> It is a cruel irony that those charitable health care providers that do not demand federal financial support would be excluded by federal regulation from access to deeply discounted drugs. Planned Parenthood cannot imagine that this was Congress' intent in passing §6001(d).

approximately 400,000 patients a year.<sup>6</sup> These worthy entities need CMS to define and apply the safety net provider definition to be eligible for nominal pricing, a critical factor in their continued operation. Please make no mistake, many of these health centers depend very heavily on nominally priced oral contraceptives, and will shut their doors in a matter of months if CMS does not reverse its position on this point.

Second, the Proposed Rule suggests that best prices will rise and state Medicaid programs will suffer lower rebates if other safety net providers are permitted to purchase at nominal prices. Proposed Rule at 77185. We do not believe this to be the case. There will be no effect on best price and Medicaid rebates of including non-340B safety net providers like Planned Parenthood affiliates in the NPE. Many of our affected affiliates have been told by drug manufacturers that in light of the Proposed Rule, they will have to pay list or market rates (WAC) for brand oral contraceptive drugs. These rates are significantly higher than nominal rates, and even higher than the price paid by large commercial for-profit entities. Manufacturers will simply not offer best price eligible pricing to nonprofit safety net providers -- they will raise (in this case dramatically) the prices offered to NPE ineligible entities to avoid the attendant Medicaid rebate liability. By including other safety net providers in the NPE, CMS will not forego new best prices. It follows that Medicaid rebates will not fall as a consequence. Expanding access to nominally priced drugs to non-340B safety net entities will not cost any federal, state or local government a dime -- the cost of these sales will be borne exclusively by drug manufacturers.

Third, as the Finance Committee inquiry demonstrates, and the Proposed Rule notes, the use of nominal pricing as a marketing tool is contrary to the intent of the NPE. The fact that such abuse has occurred in the past, however, when the NPE was open to any and all purchasers, does not suggest that expansion of the NPE to include non-340B safety net providers will perpetuate the abuse. It is telling that the Finance Committee itself, arguably the most active opponent of NPE abuse, urges CMS to define and apply the fourth category of NPE-eligible entities. Finance Letter at 2. There is risk of abuse in permitting any entity to purchase at nominal prices; Congress appears to believe, however, that the benefit of supporting the nation's network of safety net providers with low drug prices outweighs any such risk. Finally, there are better mechanisms than exclusion of non-340B safety net providers from NPE to prevent and detect abuse of the NPE.

#### CMS Should Define and Apply the Safety Net Provider Category

Planned Parenthood recognizes that crafting a workable definition of an NPE eligible safety net provider is a difficult task. Nevertheless, CMS is charged with this responsibility by the DRA, and cannot simply refuse, as it has done in the Proposed Rule.

The definition must be broad enough to cover all appropriate entities, while at the same time sufficiently detailed to avoid wholesale application and invite abuse. It must be mindful of

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<sup>6</sup> For example, Planned Parenthood serves 15% of all Colorado women in need of contraceptive services and supplies (which is roughly 33% of women in need of *publicly* funded contraceptive services and supplies).

those characteristics that make a health care provider a "safety net provider to which sales of [] drugs at a nominal price would be appropriate" based on the four factors. The integrity of the exception must be maintained by a definition that is respectful of the concerns raised by the Finance Committee regarding marketing abuse. Finally, the definition has to be specific enough to give clarity to drug manufacturers about which entities are and are not eligible for nominal pricing. Planned Parenthood appreciates this opportunity to suggest to CMS a framework for achieving all these ends.

In light of (1) specific Congressional intent from the early 1990's that nominal pricing be available to Planned Parenthood, *supra* at 2; (2) the Finance Committee's recent citation of that authority in its letter to CMS urging the definition and application of the fourth category, Finance Letter at 2; and (3) the harm that would be suffered by hundreds of thousands of patients at Planned Parenthood facilities around the country if the facilities are not returned to NPE eligibility, Planned Parenthood proposes that any definition be sure to include all Planned Parenthood affiliates and health centers. After all, family planning clinics such as those operated by Planned Parenthood affiliates are considered "core safety net providers" by the Institute of Medicine ("IOM") in its 2000 treatise on America's Health Care Safety Net. According to the IOM, "core safety net providers" are a key subset of the nation's broader health care safety net and play a critical role in providing services to the nation's most vulnerable populations. Such a definition, as detailed below, would also capture other similarly situated providers of safety net medical services.

A "safety net provider" eligible to purchase drugs at nominal prices under §6001(d) of the DRA should be a:

- (1) non-profit organization;
- (2) comprised of an outpatient clinic or several clinics;
- (3) that offers access to health care services to patients without regard to their ability to pay; and
- (4) a majority of whose patients are at 200% or less of the Federal Poverty Level.

We believe this definition to be both appropriate and workable. It squarely addresses three of the four statutory factors<sup>7</sup>: (I) the type of facility or entity (non-profit outpatient clinics that offer access to care without regard to the patient's ability to pay), (II) the services provided by the facility or entity (health care) and (III) the patient population served by the facility or entity (a majority at 200% or less of the FPL). It is designed with reference to the concerns of the Finance Committee with regard to NPE abuse in that it focuses on non-profit entities that provide services predominantly to the most needy, and it excludes hospitals which were noted to be the primary recipients of nominal pricing offered by manufacturers that abused the NPE. Finance Letter at 9-10. Furthermore, it provides a bright line for eligibility based on the

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<sup>7</sup> We do not believe the fourth factor, proximity to other safety net providers, is easily administrable and urge CMS to consider that factor only on a case-by-case basis for providers who do not otherwise meet the terms of the definition as established. For example, a *for-profit* facility 100 miles from any other NPE eligible facility may qualify to purchase drugs at nominal prices.

percentage of patients below 200% of the FPL.<sup>8</sup> A group of clinics that serve a patient population in which at least half are below 200% of FPL is clearly serving as a safety net provider of the type entitled to be eligible to purchase low cost drugs.

Planned Parenthood urges CMS to apply this definition retroactively to the beginning of 2007. Despite the Proposed Rule's non-final status, many manufacturers stopped offering nominally priced goods to non-340B safety net providers on January 1. Applying the definition retroactively would remove doubt as to the continued eligibility of the safety net providers, and assure drug manufacturers that any sales made to these entities prior to the issuance of the final rule would not set best price.

Finally, Planned Parenthood understands that central to any manufacturer's decision to offer nominally priced drugs is the question of NPE eligibility. If a manufacturer is not confident that an organization or entity is an NPE eligible entity, it will not offer that worthy safety net provider these deeply discounted drugs. The risk of unintentional best price exposure is simply too great. Therefore, Planned Parenthood urges CMS to present in its final rule a mechanism whereby drug manufacturers can be assured of a safety net provider's eligibility. This mechanism need not impose a great burden on CMS or the safety net providers to be effective. CMS could establish a simple self-certification regime for safety net providers<sup>9</sup>. When coupled with a regulatory presumption of eligibility in the absence of evidence to the contrary, we believe manufacturers would feel free to offer nominal prices to these certified providers. Alternatively, CMS could maintain a list of NPE eligible safety net providers based on individual requests for certification, as it maintains for State Pharmaceutical Assistance Programs in the best price context. Finally, CMS could maintain a registry of safety net providers eligible for NPE as the Office of Pharmacy Affairs does for 340B covered entities. Planned Parenthood simply wants to ensure that safety net providers will be eligible for the NPE, and that manufacturers will feel confident in offering it to them.

\* \* \* \* \*

In conclusion, Planned Parenthood vehemently urges CMS to reverse its position and define and apply the fourth category of NPE eligible entities, safety net providers, as required by Congress. The effect of the Proposed Rule would be to deny access to discounted drugs to many nonprofit outpatient clinics that do not enjoy federal funding, but nonetheless serve the public

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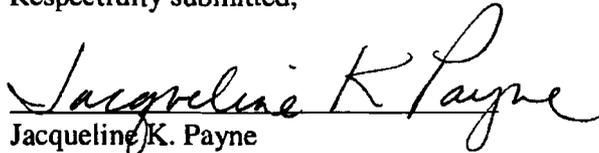
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<sup>9</sup> Like that required in the ASP reporting context, or, as established by the DRA, the certification to be required of manufacturers when reporting AMP, best price and other data (including on nominal sales).

interest. Without access to nominally priced drugs, many of these entities will be forced to close their doors. Moreover, CMS should not ignore the plainly articulated intent of Congress to include Planned Parenthood, specifically, within the ambit of the NPE. The definition of safety net provider that we have proposed is both workable and appropriate. In conjunction with a mechanism for manufacturer assurance of eligibility, inclusion of non-340B safety net providers in the set of NPE-eligible entities will ensure that literally hundreds of thousands of needy patients each year can continue to receive the free or low cost reproductive health care services they require (as Congress intended), and on which scores of communities across America rely.

Thank you for this opportunity to comment on the nominal pricing provisions of the Proposed Rule. If Planned Parenthood can be of further assistance as CMS drafts and publishes its final rule, please do not hesitate to contact me directly at 202-973-4810.

Respectfully submitted,

A handwritten signature in black ink that reads "Jacqueline K. Payne". The signature is written in a cursive style with a horizontal line drawn across the middle of the name.

Jacqueline K. Payne  
Director of Government Relations  
Planned Parenthood Federation of America

Attachment

**Submitter :** Mr. Thomas Kavanagh  
**Organization :** Nazareth Pharmacy Inc  
**Category :** Pharmacist

**Date:** 02/20/2007

**Issue Areas/Comments**

**Background**

**Background**

I own a pharmacy that has been around since 1874, though not in the family. My father was the fifth owner (1965) and I am the sixth owner (1988) during that time. I must admit, it is not looking good for a seventh owner.

**Collection of Information Requirements**

**Collection of Information Requirements**

The use of AMP will further erode the basis for small independent pharmacies. By putting Medicare Part D into the hands of the unscrupulous PBM's has caused many pharmacies to sell out or just close. Since the early 1990's, the PBM's have taken away our reimbursement through non-negotiable processes, put into place massive roadblocks to good patient care, increased paperwork for pharmacists and other health providers, and laugh all the way to the bank. They act as though it is their money even though they were created to be a middleman in the process, not the top dog above the plans, the doctors, or the pharmacists.

**GENERAL**

**GENERAL**

For the life of me, I cannot see why this administration treats small business like trash underfoot. Five and six years of college and they tell pharmacists that they cannot make a decent living and cater to their patients. Why is it always prescription drugs, which are less than 5% of total US healthcare expenditures, the first to be cut? Bush even allows people to import medications from Canada.

If you want savings, make insurance companies and the PBM's accountable to the Sherman Antitrust Act and similar measurs. Make their profits transparent so that back room deals with drug manufacturers can be seen (eg,Medco). Why does this administration not see something wrong when Medco, Caremark and Express Scripts toot their horns about 22% NET profits worth Billions a quarter? Now there should be where MAJOR cuts should be made to see any savings.

**Regulatory Impact Analysis**

**Regulatory Impact Analysis**

AMP will cut reimbursement to levels that are 36% below my invoice cost. This fact is stated by the GAO itself. Small independents pharmacies do not have the priviledge of carrying trillions of dollars of debt like the federal government. We must answer to our suppliers on a monthly and even a weekly basis. With cuts like that, people will lose jobs, charities will lose donations and patients will lose their hometown pharmacies. No amount of aggressive marketing and purchasing practices will overcome this deficit. Once the government does this, the PBM's will follow suit, adding the final nails to the coffin.

**Submitter :** Dee Simons  
**Organization :** Biogen Idec  
**Category :** Drug Industry

**Date:** 02/20/2007

**Issue Areas/Comments**

**Background**

Background  
see attachment

**Collection of Information Requirements**

Collection of Information Requirements  
see attachment

**GENERAL**

GENERAL  
see attachment

**Provisions of the Proposed Regulations**

Provisions of the Proposed Regulations  
see attachment

**Regulatory Impact Analysis**

Regulatory Impact Analysis  
see attachment

**Response to Comments**

Response to Comments  
see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

**Submitter :** Ms. Roberta Rakove  
**Organization :** Sinai Health System  
**Category :** Hospital

**Date:** 02/20/2007

**Issue Areas/Comments**

**Background**

Background

Sinai Health System is the largest private provider of health care for low-income patients in Illinois. Sinai serves some of the poorest communities in the metropolitan Chicago area. Over half of the patients treated at Sinai are Medicaid eligible and an additional 12% are uninsured. Sinai provides over \$20 million in free care each year. Sinai is also the major specialty care provider for over 50 federally qualified health center sites. The 340B program is an important asset in Sinai's ability to care for these patients. If the current regulation is enacted, Sinai could lose over \$500,000 per year in discounts for outpatient chemotherapy drugs.

**Collection of Information Requirements**

Collection of Information Requirements

Much of the benefit that Sinai receives by participating in the 340B program is derived from savings achieved by purchasing drugs for Medicaid beneficiaries at discounted 34-B prices. If outpatient clinic drugs are to be rebatable in the future, Sinai would lose the benefit of savings from the 340B program because the law prohibits subjecting manufacturers to a double discount; that is, manufacturers would not be able to be both charged Medicaid rebates and required to afford 340B discounts on the same drugs.



# Planned Parenthood<sup>®</sup> of the Texas Capital Region

February 20, 2007

Leslie V. Norwalk, Esq.  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Attention: CMS-2238-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am writing to you as the CEO of Planned Parenthood of the Texas Capital Region, a non-profit operating three health care clinics in Austin, Texas. We provide a range of high-quality, affordable preventive health services to uninsured and underinsured men, women, and adolescents in Central Texas. Our clinics serve more than 26,000 patients each year, many of whom could not otherwise afford the health services—particularly oral contraception—that we provide. In 2005, more than 62% of the well-woman exams and birth control services obtained by low-income Central Texans were provided by Planned Parenthood.

Since 1937, Planned Parenthood of the Texas Capital Region has served as a trusted provider of health care in the Austin area providing services that help to:

- Reduce the number of unintended pregnancies and abortions
- Prevent the spread of sexually transmitted infections, including HIV
- Provide early detection for cervical, breast, and testicular cancer
- Enable women and their families to plan and space their children's births

In 2005, Planned Parenthood of the Texas Capital Region provided:

- Family planning services for 17,842 clients
- Emergency contraception for 7,881 clients
- Pregnancy testing and options counseling for 3,651 clients
- Diagnosis and treatment for STIs for 6,955 clients
- Pap smears for 6,688 clients
- HIV testing for 1,479 clients
- Breast exams for 4,788 clients

**Planned Parenthood of the Texas Capital Region**  
707 Rio Grande, Austin, Texas 78701  
Phone (512) 275-0171, [www.ppaustin.org](http://www.ppaustin.org)

As a provider of high-quality, affordable health care, Planned Parenthood of the Texas Capital Region is a key part of the health safety net for low-income Central Texans. Most of our clients are uninsured, live paycheck to paycheck, and pay cash for their health services. For the majority of our clients, Planned Parenthood is their only source of health care.

Our clinics have been able to provide low-cost reproductive health care services to uninsured and underinsured Central Texans because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. If we are no longer able to purchase oral contraception at nominal prices, it is estimated that more than 50% of our clients will no longer be able to receive our services.

Planned Parenthood of the Texas Capital Region does not qualify as a 340B covered entity, despite the fact that we are a key part of the health care safety net in Central Texas. Our clients need Planned Parenthood to keep contraception affordable.

Our ability to continue to provide these valuable services rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we were deeply disappointed when CMS did not define “safety net provider” or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule. Unfortunately, like many other small safety net providers, we do not qualify for the three categories covered by the proposed rule.

We sincerely hope that the Centers for Medicare and Medicaid Services (CMS) will exercise its authority to name “other safety net providers” that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. Planned Parenthood of the Texas Capital Region is clearly a valuable safety net provider and we strongly urge CMS to include nonprofit clinics like ours in its definition of safety net providers.

Respectfully submitted by,

Kenneth S. Lambrecht  
Chief Executive Officer  
Planned Parenthood of the Texas Capital Region  
Austin, Texas

**Planned Parenthood of the Texas Capital Region  
707 Rio Grande, Austin, Texas 78701  
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# Planned Parenthood<sup>®</sup> of the Texas Capital Region

February 20, 2007

Leslie V. Norwalk, Esq.  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Attention: CMS-2238-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am writing to you as the CEO of Planned Parenthood of the Texas Capital Region, a non-profit operating three health care clinics in Austin, Texas. We provide a range of high-quality, affordable preventive health services to uninsured and underinsured men, women, and adolescents in Central Texas. Our clinics serve more than 26,000 patients each year, many of whom could not otherwise afford the health services—particularly oral contraception—that we provide. In 2005, more than 62% of the well-woman exams and birth control services obtained by low-income Central Texans were provided by Planned Parenthood.

Since 1937, Planned Parenthood of the Texas Capital Region has served as a trusted provider of health care in the Austin area providing services that help to:

- Reduce the number of unintended pregnancies and abortions
- Prevent the spread of sexually transmitted infections, including HIV
- Provide early detection for cervical, breast, and testicular cancer
- Enable women and their families to plan and space their children's births

In 2005, Planned Parenthood of the Texas Capital Region provided:

- Family planning services for 17,842 clients
- Emergency contraception for 7,881 clients
- Pregnancy testing and options counseling for 3,651 clients
- Diagnosis and treatment for STIs for 6,955 clients
- Pap smears for 6,688 clients
- HIV testing for 1,479 clients
- Breast exams for 4,788 clients

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Planned Parenthood of the Texas Capital Region does not qualify as a 340B covered entity, despite the fact that we are a key part of the health care safety net in Central Texas. Our clients need Planned Parenthood to keep contraception affordable.

Our ability to continue to provide these valuable services rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we were deeply disappointed when CMS did not define “safety net provider” or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule. Unfortunately, like many other small safety net providers, we do not qualify for the three categories covered by the proposed rule.

We sincerely hope that the Centers for Medicare and Medicaid Services (CMS) will exercise its authority to name “other safety net providers” that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. Planned Parenthood of the Texas Capital Region is clearly a valuable safety net provider and we strongly urge CMS to include nonprofit clinics like ours in its definition of safety net providers.

Respectfully submitted by,

Kenneth S. Lambrecht  
Chief Executive Officer  
Planned Parenthood of the Texas Capital Region  
Austin, Texas

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707 Rio Grande, Austin, Texas 78701  
Phone (512) 275-0171, [www.ppaustin.org](http://www.ppaustin.org)

**Submitter :** Mrs. Mary Dechow  
**Organization :** Spartan Stores, Inc.  
**Category :** Private Industry

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**Submitter :** dee simons  
**Organization :** biogen idec  
**Category :** Drug Industry

**Date:** 02/20/2007

**Issue Areas/Comments**

GENERAL

GENERAL

see attachment

1390

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

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**Submitter :** Dr. Michael Johnsrud

**Date:** 02/20/2007

**Organization :** Self

**Category :** Academic

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

**Response to Comments**

Response to Comments

CMS-2238-P-1391-Attach-1.DOC

**Date:** February 16, 2007

**Re:** File Code CMS-2238-P - Prescription Drugs

**Respondent:** Michael Johnsrud, PhD, RPh

**Background**

Thank you for the opportunity to provide my comments as part of the CMS rule-making process regarding proposed changes made by the Deficit Reduction Act of 2005 (DRA), specifically to Section 6001 of this act.

I am a pharmaceutical economics and policy researcher and hold an appointment as the Associate Director of The Center for Pharmacoeconomic Studies at The University of Texas at Austin. I have been conducting research in Medicaid prescription drug policy for a number of years, including issues related to prescription drug reimbursement, the use of preferred drug lists, the costs to dispense medication in pharmacies, and the PBM and mail-order marketplace, to name a few. As such, my comments provided below are solely my own, and do not reflect the opinions of The University of Texas at Austin or the University of Texas System.

Following are my comments with reference to the particular sections of the proposed rule changes.

**Section 447.502 (Definitions)**

I have a concern regarding the proposed definition of the "Dispensing Fee". Within the discussion, it appears that CMS will be providing a definition of the term to assist States in determining a reasonable fee. Furthermore, CMS does "not intend to mandate a specific methodology which the States must use to determine the dispensing fee."

However, within the first (1) section of the definition, the phrase "...is incurred at the point of sale.." is used. I would categorize this statement as one pertaining to the methodology of determining the cost of dispensing. Considering costs only at the point of sale seems restrictive and does not allow States to consider certain fixed costs related to dispensing a medication that would not likely be incurred at the point of sale. Since there

is language in the second (2) section of the definition that allows for "overhead associated with maintaining the facility and equipment necessary to operate a pharmacy", the phrase "...is incurred at the point of sale.." should be removed.

States should be given broad flexibility in determining the appropriate dispensing fee used in setting adequate reimbursement formulas with pharmacies. Providing guidance that appears to favor a particular methodology should be avoided.

**Section 447.504 (Determination of Retail Pharmacy Class of Trade and Determination of AMP)**

CMS is correct in acknowledging that AMP, moving forward, will likely serve two purposes: 1) rebate determination, and 2) payment guidance. Therefore, I believe CMS should proceed with caution in determining which distribution channels will be selected to determine the retail pharmacy class of trade, in order to responsibly reflect actual marketplace conditions within retail (chain and independent) pharmacy. As with the hospital and physician fee schedules that are published by Medicare and Medicaid, it is likely that the privately-funded payer community will utilize published AMP information as guidance in setting reimbursement rates for prescription drugs. Therefore, the determination of marketplace purchasing trends may have implications across the entire payer community.

I am most troubled by the definition of the term "general public" used by CMS in describing the retail class of trade. Instead of the term "general public" I would recommend that CMS consider the perspective of the "Medicaid client." In other words, the definition of the retail class of trade (for publication of the AMP) should be limited to those pharmacy distribution channels that are routinely utilized by Medicaid clients. I agree with CMS that nursing home pharmacies should not be included in the AMP calculation because: 1) it is an institutional distribution channel, and 2) as of January 1, 2006, nearly all Medicaid clients in nursing homes are now covered under Medicare Part D.

However, I would disagree with CMS regarding the inclusion of mail order and PBM channels in the retail pharmacy class of trade for publication of the AMP. To say that these

channels are utilized by the "general public" is somewhat of a misnomer, in my opinion. They are certainly not utilized by Medicaid clients. The PBMs negotiate prices with drug manufacturers and pharmacies on behalf of the "payer". These price discounts negotiated with either the manufacturer or the pharmacy may or may not be entirely passed on to the payer or the "general public."

When a prescription is dispensed by a retail (chain or independent) pharmacy and the claim is adjudicated by a PBM, it is the pharmacy, not the PBM, that assumes the risk in purchasing the drug. Pricing discounts negotiated with the manufacturer by the PBM do not pass through to the pharmacy. Therefore, to include the discounts that PBMs negotiate with manufacturers for drugs dispensed at the retail pharmacy would be an over-estimation of the discounts that retail pharmacy might achieve in the marketplace.

The majority of mail order pharmacy distribution is channeled through facilities owned by PBMs. With very few exceptions, the use of the mail order channel is limited to those patients whose employer or plan sponsor has entered into an agreement with a PBM to administrate the prescription drug benefit. Therefore, Medicaid clients do not utilize the mail order channel to any significant degree.

Furthermore, because the mix of drug products dispensed through mail order is much more narrow (mostly chronic medications) compared to the product mix observed within typical retail pharmacy (chronic and acute medications), mail order facilities achieve leveraged buying power with manufacturers and wholesalers that is not necessarily representative of the broader retail pharmacy marketplace.

In summary, including mail order and PBMs as part of the "Retail Pharmacy Class of Trade" for determination (and publication) of the AMP will likely result in unit price calculations that are much lower than those achieved by the actual retail pharmacy marketplace serving Medicaid clients.

I would, however, suggest that the nursing home, mail order, and PBM channels be included in the Medicaid Best Price determination (Section 447.505).

## **Anticipated Effects (Retail Pharmacies)**

CMS has used inaccurate assumptions with regard to estimating the impact of DRA on retail pharmacies. First, CMS has included mail order pharmacy in defining the retail pharmacy market. The inclusion of mail order pharmacy overstates the market, since mail order pharmacy will not be impacted by changes to Medicaid reimbursement per se. A more representative estimate of the 2005 retail pharmacy marketplace that excludes mail order, would be approximately \$186 billion, much lower than the \$230 billion figure used by CMS.<sup>1</sup> A five percent increase per annum places the actual 2007 estimate at \$205 billion, below CMS' figure of \$250 billion.

CMS states that the overall impact to pharmacy would be less than 1 percent of total revenue. This is a somewhat misleading statement. Assuming an \$800 million (0.4%) reduction in payments during 2007 may seem nominal on the surface. However, additional factors must be considered in order to better understand the implications of DRA to pharmacies, especially smaller independent pharmacies that dispense a majority of their prescriptions to Medicaid clients.

First of all, the distribution of Medicaid clients across pharmacies is not standardized. Pharmacies that serve a higher than average proportion of Medicaid clients will be more adversely affected. Recent data shows that, in 2005, Medicaid accounted for 23% of prescriptions dispensed within independent pharmacies, higher than the 12.6% average across all stores.<sup>2</sup>

Secondly, reducing payments for prescription drugs has a direct impact on the margin dollars (revenue minus cost of goods sold) realized to pay the expenses related to dispensing the drug. While revenue from Medicaid will be decreased, fixed and variable costs will remain the same. The result is a decrease in profitability for pharmacies that serve Medicaid clients. For example, based on an average pharmacy included in the most recent nationwide survey of pharmacy operational data, a 1 percent reduction in revenue would result in a 24.9% reduction in net profits.<sup>2</sup>

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<sup>1</sup> The Chain Pharmacy Industry Profile 2006, NACDS Foundation, Alexandria, VA.

<sup>2</sup> NCPA-Pfizer Digest 2006, National Community Pharmacists Association, Alexandria, VA.

Finally, CMS suggests that actual revenue losses would be even smaller since: 1) the majority of goods sold at pharmacies are non-prescription related items, and 2) pharmacies will switch their purchasing habits to the lower-priced AMP products. This assumption is apparently a miscalculation on CMS' part. Based on the most recent data available, non-prescription revenue in chain pharmacies is 28 percent of total sales, and only 2 percent of total sales in independent pharmacies.<sup>1,2</sup> Furthermore, to assume that pharmacies have not already developed efficient strategies to purchase medications, to date, is a naïve interpretation of the marketplace. The ability for pharmacies to further increase their purchasing power without a notable increase in prescription volume is highly unlikely.

### **Conclusion**

Above are a summary of my comments related to changes proposed by CMS with respect to the Deficit Reduction Act of 2005 (DRA), specifically Section 6001. I would welcome the opportunity to elaborate on any of my comments, as needed.

Michael Johnsrud, PhD, RPh  
Austin, Texas  
February 16, 2007

**Submitter :** Mr. Todd EVERS  
**Organization :** Mr. Todd EVERS  
**Category :** Pharmacist

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

The proposed regulations will have a very detrimental impact to retail pharmacy's ability to fill Medicaid prescriptions.

It will do one of two things to the marketplace:

1) Pharmacies will just stop filling generic Medicaid Prescriptions which will lead to decreased access for Medicaid recipients which will lead to higher and more costly Emergency Room visits and hospitalizations

or

2) Pharmacies will fill Medicaid Prescriptions for Brand name products in those categories whereby formularies contain both brand name and generic medications. This will lead to a much higher overall cost to the system!

AMP based FUL's were never intended to act as a baseline for pharmacy reimbursements. All you are getting is a new fictionalized baseline for reimbursements. Albeit much lower but you have got to make it reasonable so that there is some incentive for a pharmacist to make money. Also if you are going to go with this system you are going to have to make it "Retail Pharmacy" only. You cannot include other classes of trade (such as hospital and mail order) in your calculations!

Therefore, if these rules are implemented you will see the above mentioned scenarios in my stores.