MPhA
MASSACHUSETTS PHARMACISTS ASSOCIATION

February 16, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20

The Massachusetts Pharmacists Association (MPhA) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

Summary

MPhA continues to support federal efforts that are designed to positively affect the affordability of and access to prescription drugs and healthcare professionals. While we are supportive of these efforts, we are compelled to offer the following comments on the CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. Specifically we will comment on two sections of the proposed regulation, §447.504 and §447.510. §447.504 addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. §447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed in §447.510 creates five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself creates an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome. Additionally MPHA offers comments in response to the CMS request for comment regarding the use of the 11-Digit NDC rather than the 9-Digit NDC code. The following comments are meant to address the above-mentioned nine (9) concerns.

§447.504 Determination of AMP

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and

(iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

Comments regarding Section 6001 (c) (1) of the DRA amending 1927 (k) (1) of the Act which revises the definition of AMP as it relates to "Definition of Retail Class of Trade and Determination of AMP" state that: "We believe, based in part on the OIG and GAO reports, that retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services. As such, we would exclude the prices of sales to nursing home pharmacies (long term care pharmacies) because nursing home pharmacies do not dispense to the general public. We would include in AMP the prices of sales and discounts to mail order pharmacies."

Proposed Section 447.504(e) comprises an overly inclusive definition of "retail class of trade." The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition.

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own definition of retail pharmacy in its December 22, 2006 report entitled: *"Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs,"* the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not met by mail order pharmacies as they are not open to the public and require unique contractual relationships for service. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts, fundamentally making them different classes of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacies for medications.

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless states were to mandate mail order pharmacy. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." The following paragraphs will further address the unique contractual arrangements that distinguish mail order and PBM pharmacies from community retail pharmacies.

MPHA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public". In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. MPHA is unaware of any state that licenses PBMs, as pharmacies, to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs).

Mail order pharmacies are structurally similar to pharmacies that service nursing homes, which have been excluded in the proposed rule from the retail class of trade. Both types of operations are "closed door" in that they sell only to facilities or plans with which a contractual relationship exists. As with nursing home pharmacies, discounts and rebates that are available to mail order pharmacies rely greatly on the ability of the pharmacy to play a significant role in determining which medications are dispensed. These same types of discounts are not available to traditional retail pharmacies.

As with the nursing home pharmacies, mail order pharmacies that operate as closed door facilities should not be included in the retail class of trade. As such, we believe section 447.504(e) should be amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade.

Excluding mail order and PBM pharmacies from the definition of the retail trade of pharmacy would offer numerous benefits to pricing data and regulatory oversight, including reduced recordkeeping requirements, reduced risk of price fluctuations, and limiting the need for additional regulatory burdens. Since there would be fewer transactions, fewer records will need to be maintained by manufacturers and reported to CMS, thus reducing the reporting requirements of manufacturers. Since mail order pharmacies are most likely to participate in discounts, rebates and other forms of price concessions, the nature of these complex contractual arrangements are more likely to lead to misstatements and errors in accounting and the need for re-statement of pricing information – particularly between quarters - creating pricing volatility and fluctuations in AMP values. Excluding mail order and PBM pharmacies from AMP calculations thus assists to provide greater certainty and reliability in pricing data. Vertical integration between manufacturers and mail order pharmacies creates transactions that are not arms length and thus afford opportunities for market manipulation. In the future, CMS would likely need to redress the impact or perceived impact inherent to the conflicts of these relationships, increasing regulatory oversight burdens to ensure true market pricing data.

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that "removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29." Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to 1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to

nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

It is our belief that 447.504(g)(12) should exclude Medicaid from AMP Data. Unlike Medicare Part D and non-Medicaid SCHIP, which have private party negotiators on formularies and reimbursement rates, Medicaid reimbursement structures vary state-to-state, with some having non-market based reimbursement rates. Moreover the inclusions of Medicaid data more likely than not would create a circular loop negating the validity of AMP. Given the above statements it is clear that counting Medicaid will have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

Discounts, Rebates and Price Concessions

MPhA contends that certain discounts, rebates and price concessions found in §447.504(g)(6) and (9) should not be included in the AMP calculation. Price concessions provided by drug companies to PBM and mail order pharmacies in the form of rebates, chargebacks or other contractual arrangements which, by their very relationship, are not available to out-of-pocket customers or third party private sector parties. The proposed regulation concedes that the benefits of these rebates, price concessions, chargebacks and other contractual arrangements may not be - and MPHA asserts that they are not – shared with the community retail pharmacy networks, out-of-pocket customers, and third party payors, and, thus, they are not available to the "general public." Since PBM and mail order pharmacies (i) now often are vertically integrated with manufacturers and others in the supply chain, (ii) have contractual arrangements in many states that are not transparent in the healthcare system, and (iii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade, they are clearly distinguishable from the community retail pharmacies from which the Medicaid clients obtain their medications. For these reasons, we strongly urge CMS to consider the exclusion of mail order pharmacy rebates, chargebacks and other price concessions.

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which ultimately reduces the amount that manufacturers receive. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect

of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

This section of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed to set forth the above tasks creates five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself presents an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome. The following comments address each of these areas of concern.

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer chooses to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

As the entities engaged in the profession of pharmacy become more vertically integrated the potential for misuse of this dual reporting mechanism increases. Potentially, a manufacturer with a vertically integrated market position could use the 'rebate period' based reporting to manipulate AMP.

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[1] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.
[2] GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.
[3] §447.510(d)(2)

Additionally, the ability to estimate and apply discounts to the monthly AMP can also allow for market manipulation. The accounting involved in this dual time-frame reporting allows a manufacturer with a vertically integrated position to shift costs and revenues, in the form of discounts employed, to enhance their financial position or, worse yet, manipulate the market through a manipulation of reported AMP. Furthermore, this ability would exist for a period of three (3) years, the allowable time for revisions. This undue flexibility, afforded to find a market price, allows for market manipulation, a potential loss of price transparency and places a significant accounting burden upon the manufacturer.

'Claw-back'

Given that the proposed regulation allows substantial flexibility, with regard to financial restatement, we would recommend that CMS clearly state its intent on the ability or in-ability to recoup erroneous payments or for a provider to claim shortages based on incorrect AMPs. Since removing the manufacturers' ability to restate AMP would be too restrictive, guidance from CMS on this issue is paramount.

Pricing Lag

Under the proposed regulation, the AMP first reported to CMS could be as many as 30 days old. As such, the data will be out of date prior to dissemination to the states and the general public, a process potentially taking another 30 to 60 days. Additionally, the flexibility given the manufacturer to report discounts employed and the restatement figures will add significant variability to this lag. Material lag in AMP degrades transparency and places an undue burden upon the retail pharmacy class of trade. The technical difficulties and associated overhead burdens of limiting or eliminating this structural lag may prove to be insurmountable. Therefore, CMS should provide guidance to the states and other users of AMP on the proper method to address any issues resulting from the structural lag.

Severe Price Shifts

The inherent market volatility, associated with pharmaceutical manufacturing, occasionally results in dramatic shifts in price structure. The proposed regulation is noticeably silent in offering any mechanism to account for this fact. Severe price shifts and the significant issues associated with pricing lag can be effectively addressed with the implementation of trigger mechanisms. CMS should identify a reasonable and appropriate percentage shift in real time price that would trigger a review and recommendation by the Office of the Inspector General (OIG). It is recommended that CMS clearly define the stakeholders empowered to alert CMS of significant price shifts. Once alerted the OIG would research and then recommended an updated AMP figure to CMS. Following abbreviated review and comment by defined stakeholders, CMS would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

In its simplest form the trigger mechanism could accomplish the following: (i) limit the affects of price posting lag; (ii) mitigate potential market manipulation; (iii) mitigate a possible disincentive to fill generics by the retail pharmacies; (iv) limit incorrect public data; and (v) provide CMS with the most up-to-date calculation of AMP. The ability to adjust the posted AMP, between reporting periods, will

mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address, and mitigate, the issues surrounding pricing lag. The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the OIG will act as a damper to market manipulation. The long standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to fall below the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanism's ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic's AMP. Clearly the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

Record Keeping

The proposed regulation states in §447.510(f)(1) that "[a] manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period". This time requirement is unduly burdensome and a substantial departure from the Internal Revenue Services' seven (7) year standard for audit record keeping. We recommend that CMS adjust the record keeping requirement in the proposed regulation to be consistent with the widely accepted seven (7) year standard.

Additional Comments

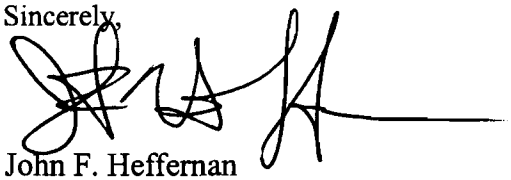
Use of the 11-Digit NDC Rather Than the 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to calculate AMP at the 9-digit level versus the 11-didgit level for generic drugs in determining FULs.

We believe that CMS should use the 11-digit AMP value to calculate the FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules, or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,



John F. Heffernan
Executive Vice President

cc: Senator Edward M. Kennedy (D-MA)
Senator John F. Kerry (D-MA)
Representative Michael Capuano (D-MA 8th)
Representative William Delahunt (D-MA 10th)
Representative Barney Frank (D-MA 4th)
Representative Stephen F. Lynch (D-MA 9th)
Representative Edward J. Markey (D-MA 7th)
Representative James P. McGovern (D-MA 3rd)
Representative Marty Meehan (D-MA 5th)
Representative Richard E. Neal (D-MA 2nd)
Representative John W. Olver (D-MA 1st)
Representative John F. Tierney (D-MA 6th)

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Office of Advocacy
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Advocacy: the voice of small business in government

February 16, 2007

Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Washington, D.C. 20201

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Medicaid Program; Prescription Drugs (71 Fed. Reg 77174, December 22, 2006)

Dear Acting Administrator Norwalk:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration.

As Chief Counsel for Advocacy, I am submitting comments on this rule because my office has received several oral and written contacts from small businesses, mostly small retail pharmacies and their representatives, that are concerned with the Centers for Medicare and Medicaid Services (CMS) proposed rule on prescription drugs.[1] The rule serves to codify requirements for drug manufacturers' calculation and reporting of average manufacturers price (AMP), and would revise existing regulations that set upper payment limits for certain covered outpatient drugs. While CMS certifies pursuant to the Regulatory Flexibility Act (RFA)[2] that the proposed rule will not have a significant impact on a substantial number of small pharmaceutical manufacturers participating in the Medicaid Drug rebate Program, and physicians and other practitioners that bill Medicaid for physician-administered drugs,[3] CMS correctly prepared an initial regulatory flexibility analysis (IRFA) and readily acknowledged that the rule will have a

[1] The rule was published in the *Federal Register* at 71 Fed. Reg. 77174 (December 22, 2006).
[2] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. § 612(a).
[3] 71 Fed. Reg. 77191 and 77192 (December 22, 2006).

significant impact on approximately 18,000 small retail pharmacies.[4] CMS admits that the savings expected to be garnered by the rule will largely be realized through lower payments to pharmacies and will likely reduce pharmacy revenues by about $800 million in 2007, increasing to $2 billion annually by 2011.[5]

The small retail pharmacy representatives who contacted Advocacy disagree with CMS' conclusion in the rule that "the aforementioned reductions in revenue, while large in absolute terms, represent only a small fraction of overall pharmacy revenues (less than 1 percent)."[6] CMS acknowledges that it was "unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."[7] While CMS should be commended for preparing an IRFA pursuant to the RFA, Advocacy believes that further analysis is required to determine how this rule will impact small retail pharmacies, especially in light of the fact that certain impacts of the rule cannot be adequately quantified.

Advocacy provides the following submission to CMS based on information provided by small pharmaceutical industry representatives:

1. **CMS should make every effort to analyze how the rule will affect small pharmacies and include the data in the final regulatory flexibility analysis.**

CMS is conceding there will be a significant impact on small independent pharmacies, but that there will only be a 1 percent impact overall on retail pharmacy revenues. The small pharmacy industry believes that this seemingly contradictory position stems from CMS analyzing retail pharmacy as a whole. CMS is not quantifying the impact specifically on small, largely independent pharmacies, especially rural independents. Since independents serve a disproportionate percentage of lower income Medicaid beneficiaries, the impact of the proposed rule is likely to be more pronounced.

2. **The application of a faulty AMP definition in calculating the Federal Upper Limits (FUL) will force many independent pharmacies to drop service to their Medicaid patients and some independents will close completely.**

The Government Accountability Office (GAO) has found that an "AMP-based federal upper limits (FULs) were, on average, 36 percent lower than average retail pharmacy acquisition costs."[8] This finding seems to validate the small pharmacy industry concern that AMP is not appropriate as a baseline for reimbursement and must be defined to reflect pharmacy acquisition cost. This lack of access to timely and safe prescription drug care will lead to additional costs of more doctor visits, emergency room care, hospital stays and long term care. Those pharmacies that remain in the Medicaid program

[4] Id. at 77191.
[5] Id. at 77192.
[6] Id.
[7] 71 Fed. Reg. 77193.
[8] See GAO report, GAO-07-239R.

may face a perverse incentive to dispense more profitable, higher-cost brand medicines, thus driving Medicaid costs higher.

3. **CMS must define AMP to reflect the actual cost paid by retail pharmacies, excluding all rebates and price concessions not available to pharmacies.**

Small pharmacy representatives told Advocacy that AMP is now to serve two distinct and contrary purposes under the proposed rule: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. GAO noted that AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates as outlined in the report "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States."[9] Small pharmacy representatives believe that all rebates and price concessions are appropriately included in "Best Price" but should not be included in AMP. Proper definition of AMP and "Best Price" will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

4. **CMS should redefine the term of art "retail pharmacy class of trade."**

Small pharmacy representatives recommended to Advocacy that the definition of "retail pharmacy class of trade" include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations. In order to be included in the definition of retail pharmacy class of trade, the prices used should be prices available to retail pharmacy and the prescriptions should be "publicly accessible." Under the suggested definition, sales to mail order facilities should not be included in AMP. Pharmacy Benefit Managers (PBMs) are not licensed to buy medications and should not be included in the definition of retail pharmacy class of trade. Mail order facilities are operated almost exclusively by PBMs, and as such they do not meet the above mentioned two criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

5. **If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the price actually paid by the retail pharmacy class of trade.**

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE[10] and to the Department of Veterans Affairs (VA). CMS also should also exclude rebates paid to PBMs from AMP calculation. The Medicaid drug rebate program was created for states to collect rebates from

[9] See GAO report, GAO-05-102.
[10] TRICARE is the health insurance program for military personnel and their families.

manufacturers in much the same way that PBMs receive manufacturer rebates on the market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive under Federal financial participation.

Conclusion

In summary, Advocacy requests that CMS give consideration to the issues raised by the small independent pharmacy industry herein and better analyze the possible affects of this regulation on that industry in the final rule. Advocacy appreciates being given a chance to provide CMS with these comments that are of great concern to small businesses in the pharmaceutical industry. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel, Linwood Rayford at (202) 401-6880, or www.linwood.rayford@sba.gov.

Sincerely yours,

Thomas M. Sullivan
Chief Counsel Advocacy

Linwood L. Rayford, III
Assistant Chief Counsel for Food, Drug
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Cc: Steven D. Aitken, Acting Administrator, Office of Information and Regulatory Affairs

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SUBMITTED VIA CMS WEBSITE / HAND DELIVERED TO CMS WASHINGTON, DC OFFICE (G. Hubert H. Humphrey Building, Room 445, 200 Independence Avenue, SW., Washington, DC 20201.)

February 20, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

Dear Acting Administrator Norwalk:

The National Community Pharmacists Association (NCPA) represents the interests of pharmacist owners, managers, and employees of more than 24,500 independent community pharmacies. These independents employ over 55,000 licensed pharmacists and over 300,000 additional employees across the United States. Independent pharmacists and pharmacies dispense approximately 42% of the nation's retail prescription drugs, with some 92% of our annual revenue coming from prescription medicines.

Many Medicaid recipients, particularly in rural and urban areas, depend on their local community pharmacies to provide them with needed medication; and CMS asked for comments regarding the "significant impact" the proposed rule would have on community pharmacies, NCPA respectfully submits the enclosed comments regarding CMS-2238-P.[1]

Medicaid comprises approximately 23% of the average community pharmacy's business. The program covers more than 50 million poor and disabled persons, over half of whom are under 18. More than half of NCPA members are located in communities of less than 20,000 persons—areas where there are fewer provider choices.

Results from a January 2007 NCPA survey show that 86% of pharmacies will seriously consider dropping out of the Medicaid program if the CMS-proposed formula goes into effect. This proposed reimbursement scheme is certain to lead to pharmacy closures, decreased patient access, poorer health and increased health care costs. If pharmacies are forced to close as a result of inadequate reimbursements, all patients—not just Medicaid patients—will suffer.

[1] Unless otherwise specified, page numbers are in reference to the 150-page print version of CMS-2238-P, found at http://www.cms.hhs.gov/MedicaidGenInfo/downloads/AMP2238P.pdf.

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For these reasons, NCPA believes that CMS should exercise the discretion granted the Secretary in the Deficit Reduction Act of 2005 (DRA, PL 109-171) to publish a final rule that does not harm patient access to community pharmacy.

We appreciate the opportunity to submit the enclosed comments on behalf of our membership and if you have any questions, please do not hesitate to contact NCPA via telephone at 703-683-8200 or via email at: Charlie.Sewell@ncpanet.org.

Sincerely,

Charles B. Sewell
Senior Vice President, Government Affairs

Enclosure

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Comments of the National Community Pharmacists Association
Centers for Medicare & Medicaid Services
42 CFR Part 447
[CMS-2238-P]
RIN 0938-A020
Medicaid Program; Prescription Drugs implementing the Medicaid Prescription Drug provisions of the Deficit Reduction Act of 2005 (DRA)

SECTION ONE – INTRODUCTION (General Comments)

The Deficit Reduction Act of 2005 (DRA) gives CMS great responsibility and latitude to define metrics that will set Medicaid reimbursements to pharmacy. CMS still has the opportunity to issue a final rule that will fairly address community pharmacy and, more importantly, will serve the interests of beneficiaries and the general public.

NCPA believes that implementation of the proposed rule would create additional long-term costs to the government which will more than offset any initial budgetary savings. The additional costs would result from pharmacy closures due to inadequate reimbursements arising from the proposed rule, which would lead to decreased timely and safe access to prescription drugs. This change will result in additional costs incurred due to more doctor visits, emergency room care, hospital stays and long term care. It is NCPA's hope that the following comments and recommendations will assist CMS in addressing beneficiary health and access issues.

If CMS does not adopt these recommendations, NCPA believes that the implemented rule will ultimately cost the government and taxpayers money, and lead to a large number of community pharmacy closures in rural America and in urban centers -- where the heaviest concentrations of Medicaid patients exist -- and significantly decrease access and the quality of health care for Medicaid patients.

It would be difficult to underestimate the negative impact of this newly proposed rule. CBO estimated that when implemented, new Federal Upper Limit (FUL) reimbursements to pharmacies based on a newly constructed Average Manufacturer Price (AMP) could reduce total Medicaid spending for prescription drugs by $3.6 billion from 2007 to 2010 and by about $11.8 billion from 2007 to 2015.[1] Including the State match, those figures worked out to some $6.3 billion from 2007-2010 and over $28 billion 2007 – 2015.[2] (The $8.4 billion in state and federal savings from 2007 to 2011 now touted by CMS includes some $4.8 billion in federal savings alone).[3] The Medicaid cuts to pharmacy reimbursements are thus heavily back loaded. Because the cuts are expected to increase in size, it is important to correctly define the metrics at this time.

In addition, the proposed cuts that community pharmacy will sustain under the DRA must be considered. In looking at just the first four years of implementation of the DRA:

- The DRA cuts federal spending by $39 billion over the first 5 (actually 4) years
- 10% of the total deficit reduction in the DRA ($3.9 billion of $39 billion) were cuts to Medicaid
- 91% of these pharmacy cuts are for Medicaid generic drugs, ($3.6 billion of $3.9 billion) though pharmacy services represent only 2% of Medicaid spending. Brand name drugs were not

[1] Congressional Budget Office Cost Estimate, S. 1932, Deficit Reduction Act of 2005, January 27, 2006, at p. 37.
[2] Id. at p. 35.
[3] Id. at 3 and at CMS Fact Sheet: Medicaid Drug Pricing Regulation Proposed, December 15, 2006, found at http://www.cms.hhs.gov/apps/media/press/factsheet.asp .

affected, even though it is more cost-effective to encourage the dispensement of relatively cheap generic drugs.

- Including the State Match, the cuts equal at least $6.3 billion over the 4 years covered by the DRA (CMS now says $8.4 billion for 2007 – 2011)
- This equals an average cost of over $30,500/year per pharmacy in these first several years – but those with a large percentage of business devoted to Medicaid patients (approximately 23% is the current average for independent pharmacy) will be more dramatically affected.

NCPA requests that the proposed rule, including: (1) CMS's concerns with potentially affecting manufacturing rebate liability to the states; and (2) CMS's choice not to lessen the impact of reducing community pharmacy reimbursement rates -- and thus patient access to Medicaid drugs -- be considered in the context of the miniscule cut to the federal budget created by this section of the DRA. This relatively small cut must be viewed in juxtaposition to the substantial harm that implementing the proposed rule would create.

SECTION TWO – KEY NCPA COMMENTS

I. Fundamental Problem of CMS's Formulation of AMP as a Measure for Reimbursement

(under II. Provisions of the Proposed Regulations – *Definition of Average Manufacturers Price – Section 447.504 at p. 21 of the CMS website version of the proposed rule and p. 77177 of the Federal Register version)*

AMP is now set to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement and 2) as an index for manufacturer rebates paid to states. **AMP was never intended to serve as a baseline for pharmacy reimbursement,** and may not have been an effective measure for manufacturer rebates as outlined in the Government Accountability Office (GAO) report, "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States" (GAO-05-102, February 5, 2005).

CMS indicates it is trying to reconcile the use of a measurement for manufacturers rebates with using that instrument as a measure for pharmacy reimbursements. This dichotomy is a strain upon an effective use of the measure that can only be resolved, in part, if CMS effectively addresses the opportunity for manufacturers to underreport AMP prices. If the CMS definition of AMP is to even come close to serving both purposes, CMS MUST define AMP to reflect only those prices available to community pharmacy, excluding all rebates and price concessions not available to pharmacy. All rebates and price concessions are appropriately included in "Best Price" but should not be included in the CMS definition of AMP.

An accurate definition of AMP and Best Price will not only lead to larger rebates to state Medicaid agencies, but will also set a more accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care and access.

If left unchanged, the end result of the proposed definition would create a perverse disincentive to dispense generic drugs. Congress assigned CMS the responsibility of defining metrics that would ensure adequate reimbursements, thus ensuring beneficiary access to community pharmacy.

To accomplish these two goals of increasing rebates to the states and encouraging the use of affordable generics through setting an accurate baseline for reimbursement rates, CMS must first define AMP so that it reflects community pharmacy acquisition costs – including accurately defining retail pharmacy class of trade and incorporating only those elements in the CMS definition of AMP that reflect pharmacy acquisition costs.

A. Retail Pharmacy Class of Trade

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 25 and p. 77178 and p. 34 and p. 77179).*

NCPA requests that CMS change its proposed definition of retail pharmacy class of trade, proposed 42 CFR Sec. 447.504(e) at p. 130 as follows:

(e) Retail pharmacy class of trade means any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, traditional chain pharmacy – including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy.

This definition currently encompasses over 55,000 retail pharmacy locations.

In order to be included in the definition of retail pharmacy class of trade, the prices used should be prices available to community pharmacy and the prescriptions should be "publicly accessible."

Under this definition, sales to mail order facilities should not be included in AMP. Mail order facilities are wholly owned and operated almost exclusively by PBMs, and as such they do not meet the above mentioned two criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

CMS's definition of retail pharmacy in this proposed regulation is inconsistent with that used in the Medicare Part D prescription drug program final rule. (*See* 42 CFR 423.100). In the final rule implementing the Medicare Part D prescription drug benefit program, the agency defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy." Thus, it would be consistent with CMS' current Part D definition of "retail pharmacy" for the agency to indicate that only sales to true retail community pharmacies represent the "retail class of trade" for the purpose of calculating the AMP.

B. Workable definition of AMP

(II. Provisions of the Proposed Regulations – *Definition of Average Manufacturers Price – Section 4447.504 at p. and p. 77177)*

In passing the DRA, Congress gave CMS the task of creating a workable definition of AMP. CMS still has the opportunity to meet this challenge.

NCPA requests that CMS adjust its definition of AMP, proposed 44 CFR Sec. 447.504(a) as follows:

(a) AMP means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include community pharmacy sales only (chain and independent) and only adjustments that reduce the actual price paid by community pharmacy.

NCPA recommends that the following elements, which community pharmacy does not receive, be excluded from the calculation of AMP:

- State supplemental, state only and SPAP prices
- FFS/depot
- Non-contingent free goods
- Discounts, rebates and price concessions to PBMs
- Prices extended to Mail Order
- Patient care programs

- Administrative Service Agreements
  - Inventory management fees
  - FFS agreements to wholesalers
- Price adjustments that do not affect the actual price paid by community pharmacy
- Other new classes of trade which receive prices not available to community pharmacy

Appropriate calculation of the AMP depends upon an accurate definition of the retail class of trade, an accurate identification of manufacturers' prices paid by wholesalers for drugs distributed to retail pharmacies, and an appropriate definition of wholesaler. CMS proposed definition has problems in all three areas.

The law clearly limits AMP calculations to prices paid by wholesalers and discounts received by wholesalers. However, CMS proposes to require that manufacturers include in the AMP calculation prices that are not paid by wholesalers, as well as discounts on drugs that are not received by wholesalers. Only payments to manufacturers by wholesalers, for drugs that are subsequently distributed to the retail class trade, can by law be included in the AMP. Any other payments must be as a matter of law, excluded from the calculation of AMP.

CMS does not follow its prior practices regarding this issue. In the preamble to the proposed rule, CMS acknowledges that for years "our position has been that PBMs have no affect on the AMP calculations unless the PBM is acting as a wholesaler...." 71 Fed. Reg. at 77179. CMS now proposes to change this current position and instead include "any" price adjustments or discounts provided by manufacturers, regardless of whether those price adjustments or discounts have anything to do with the prices paid by wholesalers. This is a complete reversal of CMS' longstanding interpretation of the statute, which clearly defines AMP as the prices paid by wholesalers.

CMS also does not follow language of the statute by including payments by non-wholesalers in calculations of AMP. CMS says "we recognize that the statute defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade...." Id. However, CMS goes on to state that "in light of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such adjustments are provided directly or indirectly by the manufacturer." This version of "Congressional intent" is not reflected in statute, and is inconsistent with CMS's longstanding interpretation of the statute.

Negotiated returned goods should also be excluded from the calculation of AMP. We recommend that CMS adopt the following policy regarding returned goods in the calculation of the AMP: "a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, which is designed to reimburse pharmacies for the replacement cost of products as well as the associated return related expenses and not designed to manipulate or artificially inflate or deflate the AMP"

These negotiated return goods policies take into consideration the unique burdens which retail pharmacies must absorb in order to effectuate the efficient return of expired pharmaceutical products to manufacturers. By mandating that only returns made pursuant to manufacturers' policies be excluded from the calculation of AMP, CMS could be voiding these negotiated return goods policies (which were negotiated in good faith between manufacturers and retailers) and are forcing retailers to accept manufacturers' policies and their inherent deficiencies.

Such action ignores that retailers absorb considerable cost through: replacement value of returns, inventory carrying cost, reverse logistics cost, and administrative expense. In order to remedy this inequity, returned goods made in good faith and pursuant to a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, must also be excluded from the calculation of AMP.

*1. **Rationale against CMS redefining AMP to instead become lowest manufacturer price***

(II. Provisions of the Proposed Regulations – *Definition of Average Manufacturers Price – Section 447.504 at p. and p. 77177)*

CMS's proposed rule is unworkable and unrealistic in that it fails to take into account community pharmacy's actual acquisition costs.

The CMS defined AMP and the resulting FUL impact not only government Medicaid programs, but now have the far reaching effect of substantially impacting the entire private market. Therefore it is essential that the FUL determination represents an accurate determination of pharmacy actual acquisition cost. Former CMS administrator McClellan already backed away from posting incorrect AMP data, stating,

> They just aren't the right numbers to use. . . We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement.[4]

In light of a recent GAO report (*GAO-07-239 Medicaid Federal Upper Limits, December 22, 2006, hereinafter "GAO report")*, it appears that CMS' initial guess at a proper FUL, based on its newly proposed definition of AMP, falls significantly short of an accurate mark. In that report, dated December 22, 2006 but not made available to the public (including NCPA) until a full month later, on January 22, 2007, the GAO issued a strong rebuttal to CMS's contention that community pharmacy could mitigate the effects of AMP-based FULs as a reimbursement measure.

The GAO report found that on average, FUL, defined as a ceiling of 250% of the lowest AMP for the chemical compound, was still on average 36% below the acquisition cost to pharmacies. Although CMS notes that rebates were not included in the GAO analysis, generally speaking community pharmacy does not receive manufacturer rebates. In the limited instances where community pharmacy does receive rebates, the amount is minimal.

Wholesalers and buying groups can choose to give – or choose not to give – pharmacies performance standard purchasing rebates out of the incentive amounts that they receive from manufacturers for purchasing drugs in patterns that benefit the manufacturer. In any case, as will be discussed in SECTION TWO, I.B.2.b., infra, any of these performance standard purchasing rebates that wholesalers choose to pass along to pharmacies do not begin to offset the average reimbursement shortfall of 36% below acquisition cost as found in the GAO report. In the case of generic drugs, community pharmacy will not even be reimbursed for the cost of the drug, let alone the cost of dispensing the prescription. The dispensing fee received from the states does not offset the considerable difference below acquisition costs reported in the GAO report.

What CMS fails to address in its response to the GAO report is the issue of generic drug availability, and how it renders CMS' scheme of lowest manufacturer's price in lieu of AMP unworkable. Smaller generic manufacturers seeking to capture additional market share are willing to enter the market with a discounted price of 20 - 30% in an effort to force pharmacies to buy their product. **The problem is manufacturing capacity**. Smaller generic manufacturers do not have the product inventories to serve more than just a percentage of the Medicaid population.

The implementation of the proposed FUL scheduled for July 1, 2007 would have a devastating impact on community pharmacies regardless if they elect to participate in the Medicaid program or not. A government defined price index that misrepresents pharmacy acquisition costs will create pricing misperceptions in the marketplace which will cause serious harm to independent pharmacies. We request that in the final rule an AMP definition that truly reflects at least real pharmacy acquisition costs be utilized in the calculation of FUL.

CMS is seeking to create a lowest manufacturing price metric to replace AMP by, for example, proposing "to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug." (p. 81). CMS asks for comment on the 30 percent rule, but to do so thoughtfully would require CMS

[4] Administrator Mark B. McClellan before NCPA's 38th Annual Legislation and Government Affairs Conference on May 22, 2006.

to reveal the additional criteria on how it proposes to implement the proposed rule. We assume, for example, that when CMS states, "We propose to adopt additional criteria to ensure that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally as presently provided in our regulations." (p. 81) that CMS is referring to 42 CFR 447.332. That regulation requires that at least three suppliers list the FDA category "A" drug for it to be eligible for inclusion on the FUL list for multiple source drugs.

2. Inadequacy of FUL – proposed 42 CFR Sec. 447.514
(II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs, pgs. 73 – 83 and pgs. 77186 – 77188)*

a. FUL is a ceiling of up to 250% of the lowest AMP

In its discussion of the type of NDC code information it will require from manufacturers reporting AMP, on p. 79 – 80 of the proposed rule, CMS makes the following statement:

> Furthermore, we expect that because the CMS defined AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased, and that to the extent it does have an impact, it would encourage pharmacies to buy the most economical package size. *(p. 79 – 80).*

That statement is simply incorrect in terms of its assertion that the new FUL ceiling is sufficient to reimburse pharmacies. (It also incorrectly implies that pharmacies are currently not motivated to buy economical packaging, a point that will be refuted in the more detailed comments in SECTION TWO, at IX, infra).

First, it is important to note that FUL is now based on a ceiling of a new measurement -- 250% of the lowest CMS defined AMP, as opposed to the previous reimbursement measure of 150% of the lowest published price of the therapeutically equivalent versions – which states typically measure through an adjustment to AWP, MAC or Best Price (BP) as set by First Databank. Prior to January 1, 2007, FUL was established for multiple-source drugs for which there are at least three therapeutically equivalent products. Since the beginning of this year, FUL is to be established for multiple-source drugs that had two or more therapeutically equivalent products.

To a lay person, a reimbursement up to 250% of an "average" metric that sounds like a retail purchasing price appears to be more than adequate. CMS must understand that a FUL ceiling of up to 250% of AMP does NOT mean that pharmacies will be reimbursed at two-and-a-half times their costs. The 250% of AMP also begs the question, "how is AMP determined?" If AMPs are numbers far below pharmacy acquisition costs, taking 250% of these numbers will not even come close to covering community pharmacy's costs for their prescriptions.

Calling the 250% a "markup" is a blatant misrepresentation of the facts. Multiplying by 250% of a low number that does not accurately reflect retail acquisition costs is a calculation in a vacuum designed only to force community pharmacy from serving their Medicaid patients.

b. CMS' measurement of FUL is inadequate
(II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs, pgs. 73 – 83 and pgs. 77186 – 77188)*

NCPA is compelled to strongly dispute CMS' contention that the new FUL under this newly proposed definition of AMP will adequately reimburse community pharmacists. Under the DRA, the FUL is to be a ceiling of 250% of the AMP for the class of generic drug at issue. *Sec. 6001 (a) of P.L. 109-171.* CMS, however, is making the FUL a ceiling of the lowest CMS defined AMP of the class of generics. In addition, not only will that actual payment typically be below the FUL, but as will be discussed in the following section c., supra, CMS is allowing the lowest AMP to be as low as only 30% of the amount of the second lowest AMP (see pgs. 81-82).

In their December report, the GAO has issued a strong rebuttal to CMS's contention that community pharmacy could mitigate the effects of AMP-based FULs as a reimbursement measure. The GAO did so by pointing out that estimated AMP-based FULs in its sample "fell below the lowest acquisition cost available to retail pharmacies." *GAO-07-239 Medicaid Federal Upper Limits at p. 16.*

The paragraph from which the above quote is taken reads as follows:

> CMS also pointed out that our study did not include an analysis of how retail pharmacies could mitigate the effects of AMP-based FULs by filing more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs. However, as part of our analysis, we compared estimated AMP-based FULs to the lowest available acquisition cost for each of the multiple-source outpatient prescription drugs in our sample. As we reported in our draft, for most [sic] the drugs in our sample—43 of 77 [56%]—the estimated AMP-based FUL fell below the lowest acquisition cost available to retail pharmacies. *Id.*

In addition: (1) 59 of the 77 drugs (77%) in GAO's sample were found to be lower than average community pharmacy acquisition costs; and (2) for the entire 77 drug sample, the estimated AMP-based FULs were, on average, 36 percent lower than average community pharmacy acquisition costs for the first quarter of 2006. *Id. at 4.*

That paragraph reads, in its entirety:

> The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs [77%] in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006. *Id.*

Two criticisms by CMS of GAO's draft report merit discussion and refutation. First, CMS incorrectly claims that community pharmacy receives rebates from manufacturers. What community pharmacies can potentially earn are purchasing rebates from wholesalers providing the pharmacy meets or exceeds certain defined performance standards.

Community pharmacy is dependent on the wholesalers choosing to reward pharmacies with some savings that the wholesalers arrange with manufacturers over the drugs due to their volume of purchases. Such performance standards might include: (1) Total dollar volume of all prescription purchases during a defined period of time; (2) total dollar volume of generics purchased during the defined period; (3) frequency of pharmacy invoice payments to the wholesalers; and (4) credit performance/history of the pharmacy. When a community pharmacy has the ability in its market to comply with purchase performance standards and receive these rebates, they are approximately 5%, if indeed any are received at all. Also *see previous discussion at SECTION TWO I.B.1. at p.6, supra.*

Perhaps even more importantly, whatever can possibly reach community pharmacies in the purchasing system in no way comes close to approaching the 36% gap that GAO found between the maximum reimbursement that pharmacies can receive under a fully utilized FUL ceiling and actual costs to acquire prescription drugs.

Second, CMS' criticism of the GAO's inclusion of outliers in calculating AMPs is a weak and inconsequential criticism of the GAO report. The footnote at the bottom of page 9 of the GAO report states that "Excluding statistical outliers from our analysis resulted in a less than 1 percent change in the average percent difference between average retail pharmacy acquisition costs and estimate[d] AMP-based FULs." *Id. at 9.* A one percent change is insignificant, and would have little bearing on the overall calculation of average community pharmacy acquisition costs.

The lowest AMP that CMS is proposing to include in the AMP calculation is also disturbing in that it creates a lowest manufacturing price metric to replace AMP. CMS proposes "to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug." (p. 81). We recommend that an 80 percent level is a much more realistic measuring point.

CMS asks for comment on the 30 percent rule, but to do so thoughtfully would require CMS to reveal the additional criteria on how it proposes to implement the proposed rule. We assume, for example, that when CMS states, "We propose to adopt additional criteria to ensure that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally as presently provided in our regulations." (p. 81) that CMS is referring to 42 CFR 447.332. That regulation requires that at least three suppliers list the FDA category "A" drug for it to be eligible for inclusion on the FUL list for multiple source drugs. Many smaller generic manufacturers should be able to meet these criteria. This problem is also exacerbated by the problem of shortages of drugs, discussed earlier in SECTION TWO – I.B.1., supra.

Finally, CMS must provide an appeals mechanism to allow providers and states an opportunity to seek removal or modification of an FUL which is not consistent with changing market conditions.

NCPA has been unable to find anyone in the industry that believes that the new FUL metric will be sufficient to adequately reimburse community retail pharmacists for their drug costs. While CMS incorrectly claims that the new FUL will sufficiently cover acquisition costs, CMS makes it clear that states are free to pay pharmacies more than what the federal government will give to the states. CMS acknowledges that the states need to make up the difference between this new metric and what pharmacists have received in the past from state Medicaid programs. Where are the states supposed to find this new funding? This amounts to another unfunded mandate being handed to the states.

c. **CMS is setting an unrealistic threshold for Outlier Prices in the FUL calculation**

(II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs, at pgs. 81 – 83 and pgs. 77187 – 77188)*

CMS proposes to set the FUL based on the lowest AMP, as long as that AMP is not more than 70 percent below the second lowest AMP for that drug. (p. 81). CMS somehow reasons that this standard will "further safeguard to ensure" that "a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs." Id. In other words, CMS will only exclude the lowest "outlier" AMPs that are more than 70% lower than the second lowest AMP for the drug – so a lowest AMP as low as $3 could serve as the AMP used to calculate FUL if the next lowest AMP was up to $10.[5]

[5] CMS thought it was worth criticizing GAO for excluding outliers in its estimated calculation of AMP-based FULs. GAO responded to the criticism by concluding that based on the numbers provided by CMS, excluding outliers from the analysis

CMS is therefore proposing to create a FUL based on possible situations where a solitary manufacturer's AMP could very well become the AMP used in the calculation of the FUL for a particular drug, even though a vast majority of the manufacturers for that drug have set an AMP that is over three times the value of the lowest AMP of a manufacturer of the drug.

It is not logical to set an exclusion of outliers at an AMP that is so much less (70%) than the next lowest AMP. A 20% figure is a more acceptable threshold level (so as low that an $8 AMP could serve as the basis for FUL if the next lowest AMP was $10).

Finally, as nominal pricing will be included in the calculation of AMP (p.131), CMS needs to explain how that decision does not in effect make the outlier price discussion moot for nominal pricing based drugs.

II. CMS has not provided drug pricing data on a confidential basis to the affected parties and thus our response to the proposed rule is based on the new GAO study and on communications with industry sources as to what AMP prices will be. This severely handicaps NCPA's ability to fully comment on the proposed rule.

(I. Background – *Changes Made by the Deficit Reduction At of 2005 at p.8, p. 77175)*

CMS has never, despite repeated requests from pharmacists and many sectors of the pharmaceutical industry, distributed on a confidential basis AMP data. The GAO Report states it simply, and perhaps best: "Because these data are not publicly available, retail pharmacies cannot determine what the relationship will be between AMP-based FULs and the prices the pharmacies pay to acquire these drugs." *GAO-07-239R Medicaid Federal Upper Limits* at p. 2. (Footnote omitted).

CMS is asking for specific examples of the "significant impact" of the proposed rule upon community pharmacy (see pgs. 108 – 109, p. 77192 under **V. Regulatory Impact Analysis**. B.3. Impact on Retail Pharmacies) despite choosing not to provide even limited AMP data. It is nearly impossible to accurately comment on the effect of the proposed definition of AMP and to provide CMS with real examples of the impact of the proposed rule without the use of actual AMP numbers. NCPA looks forward to CMS providing AMP data so that it can in turn provide CMS with the price-based specific examples that it is seeking. In the meantime, the GAO study is by far the best information available to the public. **Based on an extrapolation of the GAO findings, the CMS definition of AMP approximates only 25% of pharmacy acquisition costs.**

III. CMS's Costs Savings Estimates Ignore Increased Costs
(V. Regulatory Impact Analysis, p. 93, p. 77190)

The estimated $8.4 billion over five years - $8 billion of which would be borne by community pharmacy – does not take into account the very real potential additional costs to the government (taxpayers) through additional payment through disincentives to dispense generics. Before the implementation of Medicare Part D began, published numbers from generic manufacturers indicated that for every additional 1% of brand name drug use under Medicaid that moved to generics, some $475 million in savings would be realized.[6] Now that the dual eligibles are captured under Part D, that figure is not as large, but still quite significant. The new figure is estimated to be well over $300 million.

Considering the level of generic drug use as a percentage of all drugs under Medicaid in 2005 varied between some 42% - 61% among the states, there are potentially large monetary losses that will be incurred by creating disincentives to prescription generic drug use – and corresponding large potential savings that could be

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resulted in a less than 1 percent change in the average percent difference between average retail pharmacy acquisition costs and estimate AMP-based FULs.

[6] http://www.gphaonline.org/AM/Template.cfm

realized by incentivizing generic drug use. Unfortunately, the proposed rule penalizes generic dispensing and rewards brand dispensing.

In addition, pharmacy closures, or the suspension of Medicaid program participation caused by inadequate Medicaid reimbursements could lead to decreased timely and safe access to prescription drugs. This will also lead to additional costs of more doctor visits, emergency room care, hospital stays and long term care. Patients who do not have access to their community pharmacy will often go without their medications until their health deteriorates and they are forced to seek out much higher cost health care options.

IV. According to the CBO, CMS's Costs Savings Assume that States Will Increase Their Dispensing Fee. If the States do not do so, then pharmacy reimbursements will be so inadequate that most pharmacies will not be able to participate in the Medicaid Program.

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176 and **V. Regulatory Impact Analysis.** F. Conclusions at p. 119, p. 77195*)*

From *Congressional Budget Office Cost Estimate, January 27, 2006, S. 1932 Deficit Reduction Act of 2005 Conference agreement, as amended and passed by the Senate on December 21, 2005*:

Based on administrative data on AMPs and prescription drug spending by Medicaid, CBO estimates that those provisions would reduce Medicaid spending by $3.6 billion over the 2006-2010 period and $11.8 billion over the 2006-2015 periods. **Those savings reflect CBO's expectation that states would raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid.** The estimate also accounts for lower rebates from drug manufacturers resulting from increased use of cheaper generic drugs. *p. 37 (emphasis added).*

CBO does not reveal to what degree it "expects" states to raise dispensing fees when it calculates its numbers. Even if states were to double their dispensing fees – which is improbable -- the total reimbursement to community pharmacy would be far below their acquisition costs and their cost to dispense. Finally, for community pharmacies to stay in business, the reimbursements must include at least a small profit margin.

A study recently completed by one of the 4 largest world-wide accounting firms, Grant Thornton, has found that the average cost to dispense in the nation was $10.50.[7] Grant Thornton is a respected accounting firm that used industry-accepted accounting standards and methods. The study was based on responses from over 23,000 pharmacies and the response size was large enough that separate cost-to-dispense measurements were computed for 46 states. As the current average cost to dispense fee among the states is only $4.50, states will be highly challenged to provide an adequate reimbursement to pharmacies, consistent with the documented cost.

V. Retail Pharmacy Class of Trade should be defined as only retail pharmacies. The definition should not include PBM mail order operations, which dispense almost no Medicaid prescriptions.

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 25 and p. 77178 and p. 34 and p. 77179).*

The Omnibus Reconciliation Act of 1990 through amended Section 1927 of the Social Security Act (the Act), created the Medicaid Drug Rebate Program. The rebate legislation became effective on January 1, 1991. **CMS states that the program affords state Medicaid programs the opportunity to pay for drugs at discounted prices similar to those offered by pharmaceutical manufacturers to other large purchasers.**

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[7] *Grant Thornton LLP: National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, January 26, 2007 (hereinafter "Grant Thornton Study"). This figure is independent of the ingredient cost of the drug. Conducted by the accounting firm Grant Thornton, LLP, the study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.*

The rebate agreement attaches to single-source drugs (new, under patent with no generic equivalents) and innovator multiple-source drugs (drugs that have new-drug FDA approval for which generic equivalents exist). **This rebate agreement includes non-innovator multiple-source drugs. (FDA approved new drug generics)** The basic rebate formula for new drug generics is 11% of AMP.[8]

Since it has been repeatedly stated by CMS that AMP should reflect and look like what large purchasers in the private market pay for drugs, then retail AMP should not include price concessions, and rebates to PBMs and mail order pharmacies for which the rebate is designed to offset. No entity in the private market place receives a rebate off of the rebated price. The result would be a short change to the government by receiving manufacturer rebates based on deflated AMP values which including private sector rebates. This erroneous result was clearly never contemplated by Congress.

Mail order pharmacies are operated as closed model systems that are not available to the general public, and are presently excluded from the retail pharmacy class of trade. Since a large number of Medicaid beneficiaries are children, there is more of a need for acute medication, e.g., antibiotics and pain medicine, so the mail order pharmacy model has not been found to be an efficient one and therefore has not been adopted by the majority of state Medicaid programs. Since generally speaking mail order pharmacies do not service this population, they should not be included in the definition of retail pharmacy class of trade.

Moreover, given that there is relatively no distribution of Medicaid prescriptions through mail order, including these sales and rebates would create a benchmark that would be of little use to state Medicaid directors to set reimbursement rates for retail pharmacies.

For all these reasons, NCPA asks CMS to not include PBM price concessions and mail order pharmacies in the retail pharmacy class of trade definition.

VI. PBM Transparency

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 34 and p. 77179)*

CMS writes at pages 30:

> One of the most difficult issues with PBM discounts, rebates, or other price concessions is that *manufacturers contend that they do not know what part of these discounts, rebates, or other price concessions is kept by the PBM* for the cost of its activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, *and what part, if any, that entity passes on to pharmacies.* Despite the *difficulties* of including certain PBM rebates, discounts or other price concessions in AMP, excluding all of these price concessions could result in an artificial inflation of AMP. For this reason, we propose to include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP; however, we invite comments on whether this proposal is operationally feasible. (emphasis added).

The major problem with these assertions is that community pharmacy simply does not have access to these PBM rebates, discounts or other price concessions. Not only is CMS's proposal not operationally feasible, the premise behind the reasoning is flawed and inapplicable to what actually happens in the marketplace. To rectify the situation, CMS should require transparency from PBMs. In the absence of such transparency, CMS should not include these undisclosed elements in AMP.

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[8] For innovator (brand) drugs, the rebate is the larger of 15.1% of the AMP per unit or the difference between the AMP and the best price per u it and adjusted by the CPI-U based on launch date and current quarter AMP. http://www.cms.hhs.gov/MedicaidDrugRebateProgram/.

Defining retail pharmacy class of trade as the sector of the drug marketplace which dispenses drugs to the general public and which includes all price concessions related to such goods and services, and including in the CMS definition of AMP mail order and the prices of sales and discounts to mail order pharmacies, is an approach that does not recognize what happens in mail order.

While there is a relatively small mail order component in some of the biggest chain pharmacies, the most important characteristics of mail order is that PBMs run their own mail order companies. PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore, to include the rebates, discounts, or other price concessions given the current state of non-regulation, is not warranted. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate.

CMS requested comments on the operational difficulties of tracking said rebates, discounts or charge backs. The difficulty begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.

The large PBMs have fought in both the national and state legislative arenas, to keep that information from review by the government and its clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed -- again through lack of regulation -- to self refer to its wholly owned mail order facility. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.

Only with PBM transparency can CMS accurately ascertain whether CMS's intention to "...include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade of the purpose of determining AMP" is "operationally feasible" (p. 31) – a question for which CMS seeks comments.

VII. Definition of "Dispensing Fee" Needs to be Wholly Inclusive of the True costs to pharmacists/pharmacies to dispense Medicaid drugs.

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176*)*

An adequate Dispensing Fee definition includes the true costs of: 1) valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling: communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and 2) other real costs such as rent, utilities and mortgage payments. Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Perhaps most importantly, they provide important health, safety and counseling services by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

NCPA accordingly recommends that the dispensing fee definition section of the final rule be written as follows:

42 CFR Sec. 447.502 Definitions.

Dispensing fee means the fee which--

(1) [as CMS has written]

(2) Includes pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to any reasonable costs associated with:

Staffing costs: (a) Salaries for pharmacists and technicians, and compensation to other employees such as managers and cashiers; (b) Licensure/continuing education for pharmacists and technicians.
Store operations and overhead: (a) Rent or mortgage; (b) Cleaning, repairs, and security; (c) Utilities; (d) Computer systems, software ,and maintenance; (e) Marketing and advertising; (f) Accounting, legal and professional fees; (g) Insurance, taxes, and licenses; (h) Interest paid on pharmacy-related debt; (i) Depreciation; (j) Complying with federal and state regulations; and (k) Corporate overhead.
Preparing and dispensing prescriptions: (a) prescription dispensing materials (packages, labels, pill counters, etc.); (b) compounding the Rx when necessary; (c) special packaging (unit dose, blister packs, bingo cards and special supplies (syringes, inhalers).
Assuring appropriate use of medication: (a) drug use review; (b) consumer/patient counseling; (c) consulting with prescribers, (d) disease management, and (e) education/training.
A reasonable profit margin to ensure business viability

VIII. The Dispensing Fee is inadequate

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176*)*

The dispensing fee is the amount that state Medicaid programs add to the reimbursement formulas (typically AWP, WAC or BP) to try to total an adequate reimbursement amount for pharmacies. Currently that amount is approximately $4.50 per dispensed prescription with some states providing a slightly higher dispensing fee for generics to encourage the use of these lower priced medicines.

The Grant Thornton comprehensive study found that the average cost to dispense a Medicaid prescription in the United Sates is $10.55. CMS' definition of dispensing fee, discussed in SECTION TWO, VII, supra, must therefore be adjusted as proposed by NCPA in order to avoid (1) creating a perverse disincentive to dispense relatively inexpensive generics, and (2) increasing the likelihood that a pharmacy will no longer be able to participate in the Medicaid program because reimbursements will not fully cover the cost of the drug, pharmacy operations costs, and the opportunity to secure a reasonable profit.

IX. NCPA supports the use of NDC 11-digit codes for reimbursement purposes

(II. Provisions of the Proposed Regulations – *Definitions – Section 447.502 – National drug code at p. 19, p. 77177 and Upper Limits for Multiple Source Drugs – Section 447.514 at pgs. 81 – 83 and pgs. 77187 – 77188)*

CMS states that the "National drug code (NDC) would be defined as it is used by the FDA and based on the definition used in the national rebate agreement. For the purpose of this subpart, it would mean the 11-digit code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code)" (p. 19, p. 77177).

NCPA agrees with the need for requiring an 11-digit, product size specific NDC when reporting/acquiring AMP data. Identifying package size for reimbursement purposes should lead to more accurate measurement of acquisition costs – i.e. the cost to pharmacy to purchase the medications.

CMS mischaracterizes community pharmacy's perspective on the 9 v. 11 digit NDC issue

(II. Provisions of the Proposed Regulations - *Upper Limits for Multiple Source Drugs – Section 447.514 at pgs. 81 – 83 and pgs. 77187 – 77188)*

CMS made the following statement regarding "encouraging" pharmacies to buy economical package sizes:

> Furthermore, we expect that because the CMS defined AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased, and that to the extent it does have an impact, it

would encourage pharmacies to buy the most economical package size. (pgs. 79 – 80, p. 77187).

NCPA wishes to make clear that community pharmacies are already motivated by both the desire to obtain appropriate package sizes that will best allow the pharmacist to help beneficiaries and also by economy of scale concerns. Community pharmacists operate under tight margins, so they constantly pursue the most economical purchasing options.

Pharmacies already do look to switch to purchasing lower cost drugs to save their patients money and will continue to do so where the lower price drugs are not outdated (less effective and less safe) and are appropriate for use by their patients.

For example, a community pharmacy would like to buy drugs in 1000-pill package sizes in order to take advantage of whatever economies of scale that exist with the larger package size. Certain pharmacies, however, might need to buy 100-pill package sizes of a certain medicine as they simply might not have the sales in a particular market to justify a high volume purchase. A pharmacist that bought the 1000-pill size for such a medication might have to destroy significant amounts of unsold medications. In these situations, switching to an 11-digit NDC would fairly reflect the purchasing situation of certain pharmacies. Simply put, the most economical decision in such cases is to purchase the smaller size.

In reality, the economies of scale for many medications often do not vary between 100 and 1000 pill size containers. However, some dramatic differences in price can be found between, e.g. a 15 ml. and 5 ml. size container of eye drops, and for topical products.

Finally, it must be remembered that the dosage of the medication is dictated by the doctor-chosen prescription.

It should be clear that the issue for independent community pharmacists is adequate compensation, as opposed to motivating them to do something that CMS incorrectly assumes they otherwise would not have done. NCPA therefore favors utilization of the 11 digit NDC in order to obtain price accuracy resulting from package size specificity.

X. Reporting period should be at least Weekly, and NCPA advocates implementation of smoothing/rolling of data

(II. Provisions of the Proposed Regulations – *Requirements for Manufacturers – Section 447.510 at pgs. 65 – 73, pgs. 77185 - 77186)*

There are frequent, sudden changes in drug prices that are not accurately captured by the currently contemplated reporting period. Indeed, prices change on a daily basis, reflecting market palace availability and the number of manufacturers supplying the product in question.

CMS, however, proposes at p. 69 (p 77185) that manufacturers must submit monthly AMP to CMS by 30 days after each month, and it requires AMP, best price, and customary prompt pay discounts on a quarterly basis (presumably within 30 days of the end of each quarter). In addition, CMS states that manufacturers can rely on estimates regarding the impact of their end-of-quarter rebates or other price concessions and allocate these to their monthly AMP.

Under monthly pricing, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoicing to community pharmacy, however, continues to change daily. **NCPA requests that CMS eliminate this lengthy reporting lag period to accurately reflect the prices pharmacies must pay.**

Because of dramatic, frequent changes in drug prices, corresponding changes in AMP could negatively impact community pharmacists. Purchase prices could turn out to be significantly higher than reimbursements that are received after purchase and filling of the prescription. To lessen this unfair outcome, "smoothing" of AMP data is necessary because failure to average out AMP data could result in significant fluctuations in AMP data from month to month. CMS does not propose to develop a smoothing process for AMP data as it has for the reporting of Part B data. NCPA recommends that CMS develop a smoothing process for AMP data. A "rolling" average of AMP based on prices over the preceding 12 months is the best method to smooth out the price spikes and valleys. Spikes and valleys in AMP prices can vary significantly amongst quarters, so a 12 month average smoothing rolling period, as is done in the Medicare Part B Average Sales Price (ASP) program, is appropriate.

CMS should require manufacturers to "smooth" any discounts or rebates that are passed through by wholesalers to retail pharmacies over a rolling 12-month period. This action will reduce the potential for any significant fluctuations in AMP from quarterly and monthly calculations, and maintain some consistency in reimbursement levels. This process was developed by CMS for manufacturers' calculations of the Average Selling Price (ASP), which is used as the basis for Medicare Part B drug reimbursement. Without the smoothing process, it is very possible that upper limits for generics could be based on AMPs that are not reflective of the approximate current market prices for drugs, further reducing generic dispensing incentives.

XI. Cuts to pharmacy are much greater than CMS' characterization of a "1% loss of drug revenues" (V. Regulatory Impact Analysis – 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

CMS misleadingly, and erroneously, claims that the effect of implementation of the rule will be less than "1 percent" of prescription drug revenues.

> 3. Effects on Retail Pharmacies
> ... The savings to the Medicaid program would largely be realized through lower payments to pharmacies. As shown earlier in this analysis, the annual effect of lower FULs and related changes will likely reduce pharmacy revenues by about $800 million in 2007, increasing to a $2 billion reduction annually by 2011. These reductions, while large in absolute terms, represent only a small fraction of overall pharmacy revenues. According to recent data summarized by the National Association of Chain Drug Stores (http://www.nacds.org/wmspage.cfm?parm1=507), total retail prescription sales in the United States, including chain drug stores, independent drug stores, supermarket, and mail order, totaled about $230 billion in 2005. Assuming, conservatively, that sales will rise at only five percent a year, 2007 sales would be over $250 billion and 2011 sales well over $300 billion. Thus, the effect of this proposed rule would be to reduce retail prescription drug revenues by less than one percent, on average. Actual revenue losses would be even smaller for two reasons. First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as prescription drug sales. Second, pharmacies have the ability to mitigate the effects of the proposed rule by changing purchasing practices. The 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs. *pgs. 108 – 109, pgs. 77192 - 77193 (emphasis added).*

NCPA respectfully rebuts CMS' assertions on these pages for the following reasons:

First, for independent pharmacies, some 92% of sales consist of monies from prescription drug sales. The effect on independent pharmacies, which are disproportionately, located in the rural and urban areas that will most be affected by implementation of the proposed rule, will be tremendous and will not be abated by the small amount of non-pharmaceutical sales that occur at these pharmacies.

Second, the 1% looks at gross revenue sales figures for all of community pharmacy (chain and independent), and does not look at the Medicaid market of those pharmacies. Medicaid makes up 23% of the average independent pharmacies' business. To receive Medicaid reimbursements that are on average 36% less than acquisition costs means that many independent pharmacies will have to suspend their participation in the Medicaid program or close their doors, thus decreasing patient access, increasing health care costs, and causing the deterioration of beneficiary/patient health.

XII. NCPA requests that CMS provide AMPs on a confidential basis for the 77 multi-source medications provided to the GAO. (I. Background – *Changes Made by the Deficit Reduction At of 2005 at p.8, p. 77175)* NCPA further requests that CMS extend the comment period for an additional 60 days so our comments may reflect actual AMP data. (p. 1, p. 77174)

CMS will undoubtedly receive comments that will inform it of the nature of concerns of both community pharmacy and everyone else affected by the proposed rule. For CMS to receive at least some of the specific examples that it claims that it needs to adequately form a final rule, however, it needs to provide community pharmacy with actual AMP prices so that community pharmacy can speak with specificity as to the costs that it will bear under the proposed definition. CMS said repeatedly in CMS-2238-P that faced with uncertainty regarding the effect of a policy decision, CMS has shown concern about the potential impact on manufacturer rebate liability "precedent" in the national manufacturer rebate agreements regarding AMP when it was used as a rebate measure, and inclusion of measurement metrics in AMP. *(See, e.g., pgs. 25, 28, 32, 33, 79, 106, 107, 110, 116-118)*. The same concerns regarding potential impact of the rule should be extended to community pharmacy. The entire tone and specific policy choices in CMS-2238-P suggest that CMS would not consider making any substantive changes to the proposed rule unless it is provided specific examples that are totally dependent upon having AMP data.

Receiving the proposed rule earlier would have made it easier for all concerned parties to meet the deadlines mandated in the DRA, but CMS still has adequate time to extend the comment period and issue a final rule in time to meet the July 1, 2007 deadline.

In the proposed rule and in the March 31, 2006 CMS Roadmap to Medicaid Reform, CMS repeatedly said that access to community pharmacy, particularly in remote areas, should be preserved and that the states are free to increase dispensing fees so that community pharmacy may continue to serve their local communities.

XIII. Impact Analysis

(V. Regulatory Impact Analysis – pgs. 93 – 110, pgs. 77190 – 77193, particularly 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

The negative impacts of this rule upon independent pharmacies, Medicaid beneficiaries, and the communities they serve – particularly in rural areas – will be far greater than the impact of the implementation of the prescription drug sections of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173, MMA).

Significant Impact

CMS is conceding there will be a significant impact upon smaller independent community pharmacies, but it is still claiming that there will only be a 1% impact upon community pharmacy revenues.

This contradictory position stems from CMS analyzing community pharmacy as a whole. CMS is not quantifying the impact upon small, independent pharmacies, especially rural independents. Independents serve a disproportionate percentage of lower income (Medicaid) beneficiaries, and will thus be disproportionately impacted by the proposed rule. NCPA believes that CMS is apparently claiming that there are only Regulatory Flexibility Act (RFA) implications for small pharmacies, but it does not analyze or quantify this impact.

Offsets

There are no offsets to the negative impacts upon community pharmacy and beneficiaries. In contrast, in its RFA analysis of the MMA, CMS conceded that the shift in treatment of the prescription needs of dual eligibles from Medicaid to Medicare Part D would cause a 1 percent negative impact, but also said that the impact would be offset by overall increase in revenues due to increased prescription drug use by senior citizens.

CMS' RFA analysis that addresses the impact of implementation of Medicare Part D upon retail pharmacies, is found at pages 4498 – 4513 of Federal Register, Vol. 70 #18, January 28, 2005. The SBA's May 3, 2002 comments to CMS regarding CMS-4027-P, the SBA Office of Advocacy's comments to the proposed Part D regulations, which can be found at: http://www.sba.gov/advo/laws/comments/cms02_0503.html

The January 28, 2005 CMS document that CMS justified its conclusion that Part D would not have a "significant impact" because it projected revenue increases from projected increased drug use would offset losses.

There are no projected offsets in the proposed rule to implement the Medicaid provisions of the Deficit Reduction Act of 2005. CMS and CBO clearly state that over 90% of the revenue savings to the federal government in DRA Medicaid cuts are due to reduced reimbursements to pharmacies. CMS does not, however, offer any offsets to address the cost to taxpayers due to the negative impact upon community pharmacies and harm to beneficiary access and health. CMS has not, in other words, first even defined the projected losses. CMS also fails to make an "internal offset" of scheduled losses to pharmacy by at least directing a reasonable shouldering of the burden by manufacturers.

Independent pharmacy is disproportionately impacted

The DRA grants CMS great regulatory responsibility and discretion to make many different policy choices that will make the AMP-based rebate and reimbursement system work. It does so by, perhaps most importantly, directing CMS to create the appropriate definitions of retail pharmacy class of trade and to define the elements of AMP. By continually choosing to benefit manufacturers over community pharmacists and beneficiaries, CMS is hurting those that are least able to soften these draconian cuts yet are also the most responsible for patient health care in the Medicaid drug system.

CMS' analysis fails to consider that approximately 23% of the average independent retail community pharmacy's business is devoted to serving their Medicaid patients and that 92% of their entire business consists of prescription drug sales. The program covers more than 50 million poor and disabled persons, over half of whom are under 18. More than half of NCPA members are located in communities of less than 20,000 persons where there are fewer provider choices. Results from a January 2007 NCPA survey show that 86% of pharmacies say they are seriously considering dropping out of the Medicaid program if the CMS-proposed formula goes into effect. This proposed reimbursement scheme is certain to lead to pharmacy closures, decreased patient access, poorer health, and increased health care costs. If pharmacies are forced to close as a result of inadequate reimbursements, all patients – not just Medicaid patients -- will suffer. For these reasons, NCPA respectfully believes that CMS should exercise the discretion granted to the Secretary in the Deficit Reduction Act of 2005 (DRA, PL 109-171) to publish a final rule that does not harm patient access to community pharmacy.

It would be difficult to underestimate the impact of this newly proposed rule. CBO estimated that when implemented, setting new Federal Upper Limit (FUL) reimbursements to pharmacies based on a newly constructed AMP could reduce total Medicaid spending for prescription drugs by $3.6 billion from 2007 to 2010

and by about $11.8 billion from 2007 to 2015.[9] Including the State match, those figures worked out to some $6.3 billion from 2007-2010 and over $28 billion 2007 – 2015.[10] (The $8.4 billion in state and federal savings from 2007 to 2011 touted by CMS includes some $4.8 billion in federal savings alone).[11] The Medicaid cuts to pharmacy reimbursements are thus heavily back loaded. Because the cuts are expected to increase in size, it is important to correctly define the metrics at this time, so that manufacturers are also included in deficit reduction.

Overall Impact

According to CMS analysis, about 18,000 independent pharmacies have revenues less than $6.5 million. This classifies the majority (73%) of independent pharmacies as small businesses.[12]

As pointed out by CMS in the proposed rule, the calculation of AMP as proposed by CMS will have a "significant impact" on some small, independent pharmacies. (p. 110). However, NCPA concludes that it will have a significant impact on the entire independent pharmacy sector. Consequently, independent pharmacies have a large stake in the findings of the final small business regulatory flexibility analysis (RFA).

Anticipated Effects

We believe that they agency's initial impact analysis is flawed based on incomplete information and inaccurate assessments of pharmacy marketplace realities. Throughout our comments, NCPA has provided mitigating information to assist the agency with the final small business regulatory flexibility analysis.

Most notably, the agency's flawed analysis does not consider that independent pharmacies service a significantly higher percentage of Medicaid patients than traditional chain, grocery store and mass merchant pharmacies.

We reiterate that the agency's reasoning for potential offsets in decreased revenue in small business does not apply for the majority of independent pharmacies. First, losses due to the CMS proposed AMP definition would not be offset in front end sales because only 8% on average of total sales are non-prescription products in independent pharmacies. Second, independent pharmacies already seek the best pricing they can obtain while still maintaining quality standards. The proposed strategy to change purchasing practices when presented with a 250% of AMP benchmark that is on average 36% below acquisition costs[13] is not realistic in today's marketplace and is frankly inconsistent with quality patient care. Is CMS suggesting that a Medicaid patient wait to receive a life saving medication such as an antibiotic or heart medication until a pharmacy receives a generic in stock which has an AMP greater than acquisition cost?

The proposed definition by CMS of AMP and retail pharmacy class of trade in CMS-2738-P would have a devastating impact on the already slim operating margin in independent pharmacies. This is further heightened by that fact that independent pharmacies disproportionately serve Medicaid patients and will bear the impact of the flawed AMP definition more profoundly that traditional chain, grocery store and mass merchant pharmacies.

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[9] Congressional Budget Office Cost Estimate, S. 1932, Deficit Reduction Act of 2005, January 27, 2006, at p. 37.
[10] Id. at p. 35.
[11] Id. at 3 and at CMS Fact Sheet: Medicaid Drug Pricing Regulation Proposed, December 15, 2006, found at http://www.cms.hhs.gov/apps/media/press/factsheet.
[12] The *2006 NCPA-Pfizer Digest,* a marketplace survey of independent pharmacy both demographic and financial, places the number of independent pharmacies with annual revenues of less than $6 million at 19,600 (80%). Regardless of the figure is used; the overwhelming majority of independent pharmacies are small businesses.

[13] GAO-07-239.

XIV. Possible Exemptions of Community Pharmacy

(V. Regulatory Impact Analysis – pgs. 93 – 110, pgs. 77190 – 77193, particularly 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

CMS on pages 98 – 105 discusses its obligations under the Regulatory Flexibility Act and on pages 108 – 110, the effects on retail pharmacies. As approximately 23% of the average independent pharmacy's business is devoted to Medicaid patients (beneficiaries), implementation of the proposed rule will have a dramatic impact upon patient access and health through the suspension in participation in the Medicaid program by, or closure of, independent pharmacies caused by reimbursements that fall significantly below costs to acquire the medications needed to fill Medicaid prescriptions.

An option for reducing this impact would be to exempt community pharmacies under certain criteria. The criteria should include: 1) the SBA definition for small business based on gross dollar of business – $6.5 million annual; or 2) pharmacies that have a 10% or higher volume of Medicaid business. Those pharmacies exempt under this criteria should instead be reimbursed based on a formula that accurately reflects independent community pharmacies.

SECTION THREE – SPECIFIC COMMENTS

Rebate period (p. 20, p. 77178, under **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502*)

CMS states that because it did not find Congressional intent that the definition of rebate period would be changed from monthly to quarterly; CMS is not changing that definition. As AMP data is reported monthly for purposes of calculating the FUL and for release to States, NCPA does not find a compelling reason for leaving the rebate period as a quarterly measure. Congress did not explicitly prevent this change, and the rule is more unified if CMS makes the change.

Past policy under AMP as a rebate measure

(pgs. 27 – 28, pgs. 77178, **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502-Definition of Retail Pharmacy Class of Trade and Determination of AMP*)

CMS wrote on pgs 27 - 28 (p. 77178) of the proposed rule:

> The exclusion of prices to mail order pharmacies, nursing home facilities (long-term care facilities), and PBMs would substantially reduce the number of transactions included in the CMS definition of AMP. In addition, removal of these prices would address differing interpretations of CMS policy identified by the OIG and the Government Accountability Office (GAO) due to the lack of a clear definition of AMP or specific guidance regarding which retail prices should be included in AMP. However, such a removal would not be consistent with past policy, as specified in manufacturer Releases 28 and 29 (http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp#TopOfPage), would likely result in a higher AMP, and would result in an increase in drug manufacturers' rebate liabilities.

The sole reasons offered by CMS, therefore, for including mail order in the AMP calculation is that its removal would not be consistent with "past policy" and that it would result in "an increase in drug manufacturers' rebate liabilities."

Congress, however, has deemed that AMP will now also serve a new purpose – as a measure for reimbursement. For CMS to choose to make the measure fit merely the old purpose is to reject Congressional

intent in making AMP a measuring unit for a new purpose. "Past policy" therefore does not apply to this new use of AMP. In addition, if the purpose of the Deficit Reduction Act was to reduce budgetary costs to the federal government, it is inconsistent with the DRA for CMS to be so concerned with potential increases in manufacturers' rebate payments to the states that it reduces AMP, thus negatively impacting reimbursements to pharmacies.

Administrative and Service Fees (p. 39, p. 77180, **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502*)

This is yet another area that exists as part of AMP because of its legacy as a measure of rebates. CMS concedes that "Some believe that these fees should not be included in AMP because the manufacturer does not know if the fees act to reduce the price paid by the end purchasers." (p. 39, p. 77180). Unless there is transparency by PBMs, there is strong reason to believe that these fees do not in fact reduce the price paid by the end purchasers. Certainly retail pharmacists do not receive administrative and service fees, so NCPA's position is that they are not provided to, and should not be included in the definition of, retail pharmacy class of trade.

Direct Patient Sales (pgs. 40 – 41, pgs. 77180 – 77181, **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502*)

These are special deals in which community pharmacy does not participate, and as such, should not be included in the calculation of AMP.

Manufacturer Coupons (p. 42, p. 77181, **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502*)

CMS again shows sensitivity to an area that has been "problematic for CMS as well as some manufacturers" (p.42, p. 77181) without adequate understanding of what happens to community pharmacy. Later in the same page, CMS writes, "In this proposed rule, we propose to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP", thus including "coupons redeemed by any entity other than the consumer in the calculation of AMP."

NCPA believes that if consumer-redeemed coupons are not included in the retail pharmacy class of trade, then there is no reason to exclude those redeemed by the pharmacist, for in such cases the pharmacist is merely a pass-through entity – the pharmacist does not realize any monetary gain. As the pharmacist does not receive monetary benefit when it redeems a coupon, pharmacist-redeemed coupons should also be excluded from the calculation of AMP.

Similarly, patient assistance programs should also not be included in the calculation of AMP, as these sales have nothing to do with the price paid by the wholesaler or the pharmacy, and would inappropriately lower the AMP. For this reason, drugs provided to patients through manufacturer assistance programs should not be included in the AMP. These items cannot by law be included in the AMP because they do not reflect prices paid by wholesalers to manufacturers for drugs distributed to the retail class of trade.

Future Clarifications of AMP (p. 43, p. 77181, **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502*)

CMS intends to "address future clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS website as needed." Some areas of clarification will likely reflect policy choices, as opposed to being technical clarifications. For those more substantive areas, NCPA advocates using a regulatory, due process method of proposing and receiving comment on proposed rulemaking.

Determination of Best Price – Section 447.505 (p. 44, pgs. 77181- 77182, **II. Provisions of the Proposed Regulation)**

To obtain Medicaid coverage of their products, drug manufacturers must enter into a rebate agreement with CMS. The basic rebate formula for generics (non-innovator multisource drugs) is 11% of AMP.[14]

Pharmacists do not receive or give these rebates – the manufacturers provide them to Medicaid. CMS goes to great lengths to exercise its authority and discretion to clarify the requirements for best price. This choice stands in stark contrast to the authority and discretion which it consistently declines to exercise in several key areas of this proposed rule on areas which need clarification regarding the definition of retail pharmacy class of trade and AMP. Those refusals to exercise discretion and maintain the status quo despite clear indications of the true state of the perverse disincentive to dispense generic drugs created by the proposed rule will, if not rectified, lead to injury to patient access to Medicaid medications.

Any discussion of best price, therefore, must first note this dichotomy between CMS's treatment of best price on the one hand, and AMP and the definition of the retail pharmacy class of trade on the other.

Issues regarding best price, including the nominal price aspect of best price, are of more concern to manufacturers than to community pharmacy as the best price metric affects the levels of manufacturer rebates. CMS does, however, include nominal price in the calculation of AMP (p. 131, p. 77198), which is illogical as nominal price is a best price concept. NCPA also notes, that in the proposed rule, CMS was careful to repeatedly express concern about the potential effects on manufacturer liability when it rejected at several points defining AMP in a way that would increase pharmacy reimbursements. In contrast, the discussion of nominal pricing, CMS expresses an opposite concern on a matter that does not directly affect reimbursements: "Additionally, we believe that 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 beyond those specifically mandated by the DRA and lowering manufacturer rebates to the Medicaid Program." p. 64., p. 77184.

Finally, the inclusion of nominal price in the CMS definition of AMP appears to override the purpose of including outliers up to 30% of the next lowest AMP into the AMP calculation. CMS must clarify how it is treating these two measurements.

Electronic Submissions - *Requirements for Manufacturers – Section 447.510* **(p. 72, 77186, II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502*)

CMS proposes requiring that all product and pricing data (monthly and quarterly) be submitted to CMS in an electronic format. NCPA supports this CMS proposal. In a related issue, NCPA hopes that CMS will impose the same standard to NCPA's efforts to obtain EFT reimbursement payment from PBMs for Part D claims submitted by EFT by pharmacists.

SECTION FOUR – CONCLUSION

In order to reduce the negative impact upon patient access that will result from implementation of the Medicaid provisions of the Deficit Reduction Act of 2005 (DRA), CMS must significantly alter key provisions of CMS-2238-P. As discussed in these comments, CMS must make changes in the following areas:

1. Proposed Definitions must be significantly changed

[14] For innovator (brand) drugs, the rebate is the larger of 15.1% of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP. http://www.cms.hhs.gov/MedicaidDrugRebateProgram/.

(under II. Provisions of the Proposed Regulations – *Definition of Average Manufacturers Price – Section 447.504 at p. 21of the CMS website version of the proposed rule and p. 77177 of the Federal Register version)*

Congress gave CMS considerable regulatory authority and responsibility to create REGULATORY definitions that would adequately address the point that AMP now serves two purposes. CMS' intention to side with manufacturer interests at the expense of community pharmacy participation in the Medicaid program -- and in the pharmacy business itself – will hurt patient access and increase health care costs, thus defeating the purpose of deficit reduction. Creating an inadequate AMP-based FUL will lead to these results.

The retail pharmacy class of trade must not include PBMs and sales to Mail order facilities, and must not include elements to which community pharmacy does not have access. The elements of AMP must be restricted so that CMS does not create a lowest manufacturer price instead of an AVERAGE manufacturers price.

2. CMS must provide drug pricing data on a confidential basis to community pharmacy

Without the data, no one (except, of course, for CMS, manufacturers and state Medicaid directors) can provide CMS with the specific examples and information regarding "significant impact" that it seeks. Extrapolating from the GAO report – which utilizes data CMS provided to it - shows that the CMS defined AMP to only approximate 25% of pharmacy acquisition costs.

3. Both the costs savings estimates and the Regulatory Flexibility Act assessments must be changed as they fail to recognize the impact upon community pharmacy and the increased health care costs of Medicaid beneficiaries that implementation of the rule would cause.

(I. Background – *Changes Made by the Deficit Reduction Act of 2005 at p.8, p. 77175, and* **V. Regulatory Impact Analysis.** *3. Effects on Retail Pharmacy at pgs. 108 – 110, pgs. 77192 -77193)*

4. CBO said that CMS's Costs Savings assume that states will increase their dispensing fees – If the states do not do so, then pharmacy reimbursements will be even lower. States are not required to increase dispensing fees. **Even if they increase them to meet the Grant-Thornton calculated average dispensing fee cost of $10.50, community pharmacies will not receive adequate reimbursements because of the artificially low AMP contemplated in the proposed rule. CMS should reveal what levels of increased state dispensing fees it gave as a basis for CBO's analysis.**

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176 and **V. Regulatory Impact Analysis.** F. Conclusions at p. 119, p. 77195*)*

5. We emphasize again that retail pharmacy class of trade should be defined as only retail pharmacies. The definition should not include PBM mail order operations, which dispense almost no Medicaid prescriptions.

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 25 and p. 77178 and p. 34 and p. 77179).*

6. CMS "invite[s] comment as to whether [the following] proposal is operationally feasible": to "include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP". **Community pharmacy knows that it does not receive these rebates, discounts or other price concessions. Requiring PBM transparency will provide solid proof.**

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 34 and p. 77179)*

7. The Definition of "Dispensing Fee" Needs to be wholly inclusive of the true costs to pharmacists/pharmacies to dispense Medicaid drugs.

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176 and **V. Regulatory Impact Analysis.** F. Conclusions at p. 119, p. 77195*)*

8. CMS needs to strongly encourage the states to increase their inadequate dispensing fees, consistent with the policy it stated in its March 31, 2006 Roadmap to Reform.

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176 and **V. Regulatory Impact Analysis.** F. Conclusions at p. 119, p. 77195*)*

9. NCPA supports the use of NDC 11-digit codes for reimbursement purposes, which CMS appears to state is logical, but then backs away from implementing. Independent pharmacies are generally small businesses that have to be careful to buy the most economical packaging balanced with sensitivity to patient needs.

(II. Provisions of the Proposed Regulations – *Definitions – Section 447.502 – National drug code at p. 19, p. 77177 and Upper Limits for Multiple Source Drugs – Section 447.514 at pgs. 81 – 83 and pgs. 77187 – 77188)*

10. The reporting period should be at least weekly and NCPA advocates implementation of smoothing/rolling of data.

(II. Provisions of the Proposed Regulations – *Requirements for Manufacturers – Section 447.510 at pgs. 65 – 73, pgs. 77185 - 77186)*

11. Cuts to pharmacy are much greater than CMS' characterization of a "1% loss of drug revenues". CMS contradicts this assertion by stating that there will be a "significant impact" upon small pharmacies. CMS must place greater weight on the RFA impact upon these pharmacies. NCPA estimates that the impact of this rule on independent pharmacies and their Medicaid patients will be devastating.

(V. Regulatory Impact Analysis – 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

12. NCPA requests that CMS provide AMPs for the 77 multi-source medications provided to the GAO. NCPA further requests that CMS leave open the comment period for another 60 days so our comments may reflect actual AMP data.

(I. Background – *Changes Made by the Deficit Reduction At of 2005 at p.8, p. 77175,* and p. 1, p. 77174)

13. CMS must consider, ascertain and fulfill its RFA obligations regarding the impacts of the proposed rule upon community pharmacy.

(V. Regulatory Impact Analysis – pgs. 93 – 110, pgs. 77190 – 77193, particularly 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

14. CMS should implement the following exemptions for community pharmacies based on the following criteria: 1) SBA definition of small business based on gross volume of business; or 2) pharmacies that have a 10% or more volume of Medicaid business. Those pharmacies exempt under this criteria should instead be reimbursed based on a formula that accurately reflects independent community pharmacies.

(V. Regulatory Impact Analysis – pgs. 93 – 110, pgs. 77190 – 77193, particularly 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

41

American College Health Association

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Rec'd

February 20, 2007 FEB 20 2007

BY HAND OVERNIGHT COURIER

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, DC 20201

Attn: Kimberly Howell

Re: Comments on Proposed Rule CMS-2238P – Nominal Price Exemption (Proposed 42 C.F.R. §447.508)

Dear Ms. Howell:

The American College Health Association (ACHA) is pleased to submit the following comments to the Centers for Medicare and Medicaid Services (CMS) in response to CMS' proposed rule to implement provisions of the Deficit Reduction Act of 2005 (DRA), published in the Federal Register on December 22, 2006 (71 Fed. Reg. 77174-77200). ACHA is the only national association representing health care providers and student health centers operated by colleges and universities that provide health care services to college students. Our membership is comprised of nearly 900 health facilities of public and private non-profit universities and colleges throughout the country, and approximately 3,000 health professionals servicing many of the 17 million college students nationwide. A list of our institutional members is attached. These comments are limited to proposed 42 C39.F.R. §447.508, "Exclusion from best price of certain sales at nominal price," 71 Fed. Reg. 77198 and the impact of this proposed regulation on our constituents.

About ACHA Member Services

For many students, student health insurance provided by their college or university is the only health care coverage available to them. State laws often cut off the age at which a parent can carry a dependent on a policy and limit coverage to full time students. For this reason, graduate students may lack the means to obtain any

other health care coverage. For some members, a significant percentage of their patient population is otherwise uninsured.

Prior to the enactment of the DRA, ACHA members purchased contraceptive drugs at nominal prices and passed on the savings to students in one of three ways: The drugs were provided free of charge, at cost, or at a low price below the price of a generic version. In addition, the modest revenue from the sale of contraceptive drugs financed health promotion programs and sexual health education programs, including education concerning the health risks of AIDS and other sexually transmitted diseases, free or low cost PAP, STD, and HIV testing services, free condoms, and reduced cost of other over-the-counter and prescription medications. Since the DRA became effective, and nominal prices to college and university health centers risked setting a very low Medicaid best price for the drug manufacturers, they have ceased selling the drugs at the steeply discounted price, thereby impacting the institutions' ability to provide the same prices and level of services to the students.

Background

Pharmaceutical manufacturers must agree to pay rebates to the States on prescription outpatient drugs reimbursed by the Medicaid program as a condition of payment under the program. For innovator drugs, frequently referred to as brand drugs, the rebate formula is based on the difference between the Average Manufacturer Price (AMP) and "best price," or 15.1%, whichever is greater. Accordingly, a very low best price will result in a large unit rebate amount. Because the Medicaid program can represent 15% of the U.S. market for a covered prescription drug, manufacturers are disinclined to provide deep discounts if it will establish a low price.

When it enacted the Medicaid rebate statute, Congress recognized this potential consequence could negatively affect historical practices in which drug manufacturers sold deeply discounted drugs to health care providers treating low income patients. Availability of deeply discounted prices for birth control medication was specifically cited during the debate as an example of the concern Congress sought to address. In order to protect these arrangements, Congress excluded from the calculation of Medicaid best price drugs that were sold at "nominal price." CMS defined nominal price to mean a price that calculated at less than 10% of AMP.

ACHA members were among the entities that had historically received oral contraceptive drugs from manufacturers at deeply discounted prices. The nominal price exemption from best price allowed manufacturers to continue the practice, because, without it, they would not extend the deep discounts to 15% of their market. As discussed, our members and their patients benefited enormously from nominally priced drugs.

In recent years, Congress became concerned that some manufacturers were abusing the nominal price exemption by providing low-cost drugs to commercial customers as a strategic, marketing tool. In particular, Congress was concerned that private, for-profit hospitals were receiving nominally priced drugs in exchange for

guaranteed market share and similar arrangements. This led to a decision to limit the sales at nominal price that qualified for the best price exclusion. Through its investigation, Congress was aware of certain categories of non-profit entities that historically had relied on nominally priced drugs to provide health services, and it named these in the statute, but it included a fourth category of unspecified entities, and intended for CMS to identify other entities who depended on nominal prices and would be harmed if such prices were no longer available to them.

ACHA members should be included in proposed 42 C.F.R. §447.508

In its proposed rule, CMS declined to add any other categories of safety net providers to the Nominal Price Exemption. On behalf of all our members, and for the reasons discussed below, we urge CMS to add the following fourth category to the proposed section 447.508:

(4) An entity at an institution of higher education the primary purpose of which is to provide health services to students attending the institution.

It appears from the preamble to the proposed rule that CMS did not apply the statutory criteria to determine whether any other safety net providers should be included in the nominal price exemption. Rather, CMS made a categorical decision not to expand the list beyond the three categories of providers identified by Congress. In the preamble, CMS explained its decision was based on concerns that manufacturers would continue to use nominal sales as a marketing tool. However, by specifying criteria for determining appropriate exemptions, Congress intended for CMS to evaluate arrangements with safety net providers and balance the public benefit from the sale of nominally priced drugs to these providers against indirect benefits to the manufacturers. If CMS evaluates nominal price arrangements with college health centers, it is evident that these sales should be exempt from best price.

None of the concerns that prompted Congress to restrict the nominal price exemption are present in the case of contraception sales to college and university health centers. Our members are either public or private, not-for-profit, institutions many of whom have patient populations with limited income, or are often uninsured, or lack coverage for contraceptive drugs, except (in some cases) through the facilities' student health plans, which the facilities provide by contracting with outside insurers or through self-insurance. The sales of contraceptive drugs at nominal prices are not contingent on market share agreements or the purchase of other products.

If our facilities are not included in the final rule, there will be short term and long term adverse consequences for the facilities and the students. First, as contraceptive drugs are dispensed to a large number of students, the facilities will have to increase their prices, which are currently below the pharmacy benefit co-pay amount and the cost of generic equivalents. Second, as drug prices go up, where a student health plan covers contraception, premiums will go up drastically to adjust for the claim experience. Members who are self-insurers will be faced with the choice of increasing premiums or consuming reserves. Third, facilities will have to reduce the availability of free or low

cost health care programs and services that help prevent the spread of sexually transmitted diseases and detect HIV and cancer at early stages. Fourth, students, who often work at low paying jobs to defray the high cost of higher education, will have to pay more out of pocket or try and find a 340B clinic in their area to access affordable contraception. Many students simply cannot afford increases in the cost of their contraceptive drugs in the face of sharp increases in the cost of their education. In the long run, the high cost of drugs and services and logistical problems will undoubtedly lead to reduced testing and use of contraception and a higher rate of unintended pregnancy, undetected health problems, and untreated gynecological disorders.

Again, we urge you to amend the proposed rule to exclude from best price sales at nominal price to an entity at an institution of higher education the primary purpose of which is to provide health services to students attending the institution.

Thank you for your consideration. We will be pleased to respond to any questions you may have concerning these comments.

These comments are respectfully submitted on behalf of the President and Board of Directors of the American College Health Association.

Sincerely,

Doyle E. Randol, MS, Col. USA (Ret.)
Executive Director

American College Health Association

Member Institutions

State	Institution	City
AK	University of Alaska - Anchorage	Anchorage
AK	University of Alaska - Fairbanks	Fairbanks
AK	University of Alaska - Southeast	Juneau
AL	Alabama A & M University	Normal
AL	Alabama State University	Montgomery
AL	Birmingham-Southern College	Birmingham
AL	Jacksonville State University	Jacksonville
AL	Samford University	Birmingham
AL	Spring Hill College	Mobile
AL	Troy State University	Troy
AL	University of Alabama - Birmingham	Birmingham
AL	University of Alabama - Huntsville	Huntsville
AL	University of Alabama - Tuscaloosa	Tuscaloosa
AL	University of Montevallo	Montevallo
AL	University of North Alabama	Florence
AL	University of South Alabama	Mobile
AR	Arkansas State University	State University
AR	Arkansas Tech University	Russellville
AR	Henderson State University	Arkadelphia
AR	Lyon College	Batesville
AR	Southern Arkansas University	Magnolia
AR	University of Arkansas - Fayetteville	Fayetteville
AR	University of Arkansas - Little Rock	Little Rock
AR	University of Arkansas - Monticello	Monticello
AR	University of Central Arkansas	Conway
AZ	Arizona State University	Tempe
AZ	Arizona State University - Polytechnic Campus	Mesa
AZ	Arizona State University - West Campus	Glendale
AZ	Arizona Western College	Yuma
AZ	Embry-Riddle Aeronautical University	Prescott
AZ	Grand Canyon University	Phoenix
AZ	Northern Arizona University	Flagstaff
AZ	University of Arizona	Tucson
CA	Allan Hancock College	Santa Maria
CA	Azusa Pacific University	Azusa
CA	Biola University	La Mirada
CA	Butte College	Oroville
CA	Cabrillo College	Aptos
CA	California Institute of Technology	Pasadena
CA	California Lutheran University	Thousand Oaks
CA	California State Polytechnic University - Pomona	Pomona
CA	California State University - Bakersfield	Bakersfield
CA	California State University - Chico	Chico

State	Institution	City
CA	California State University - East Bay	Hayward
CA	California State University - Fresno	Fresno
CA	California State University - Fullerton	Fullerton
CA	California State University - Long Beach	Long Beach
CA	California State University - Monterey Bay	Seaside
CA	California State University - Northridge	Northridge
CA	California State University - Sacramento	Sacramento
CA	California State University - Stanislaus	Turlock
CA	Cerritos College	Norwalk
CA	Citrus College	Glendora
CA	College of San Mateo	San Mateo
CA	College of the Canyons	Santa Clarita
CA	College of the Sequoias	Visalia
CA	Columbia College	Sonora
CA	Crafton Hills College	Yucaipa
CA	Cuesta College	San Luis Obispo
CA	Cuyamaca College	El Cajon
CA	De Anza College	Cupertino
CA	Dominican University	San Rafael
CA	Evergreen Valley College	San Jose
CA	Foothill College	Los Altos
CA	Fresno City College	Fresno
CA	Fresno Pacific University	Fresno
CA	Fullerton College	Fullerton
CA	Golden West College	Huntington Beach
CA	Grossmont Community College	El Cajon
CA	Hastings College of Law	San Francisco
CA	La Sierra University	Riverside
CA	Las Positas College	Livermore
CA	Los Angeles Pierce College	Woodland Hills
CA	Loyola Marymount University	Los Angeles
CA	Marymount College	Rancho Palos Verdes
CA	Merced College	Merced
CA	Mission College	Santa Clara
CA	Modesto Junior College	Modesto
CA	Moorpark College	Moorpark
CA	Napa Valley College	Napa
CA	Occidental College	Los Angeles
CA	Ohlone College	Fremont
CA	Pacific Union College	Angwin
CA	Pepperdine University	Malibu
CA	Riverside Community College	Riverside
CA	Saint Mary's College of California	Moraga
CA	San Bernardino Valley College	San Bernardino
CA	San Diego Miramar College	San Diego
CA	San Jose City College	San Jose

State	Institution	City
CA	San Jose State University	San Jose
CA	Santa Barbara City College	Santa Barbara
CA	Santa Clara University	Santa Clara
CA	Santa Rosa Junior College	Santa Rosa
CA	Santiago Canyon College	Orange
CA	Shasta College	Redding
CA	Sierra College	Rocklin
CA	Simpson University	Redding
CA	Stanford University	Stanford
CA	The Claremont Colleges	Claremont
CA	University of California - Berkeley	Berkeley
CA	University of California - Davis	Davis
CA	University of California - Irvine	Irvine
CA	University of California - Merced	Merced
CA	University of California - Riverside	Riverside
CA	University of California - San Francisco	San Francisco
CA	University of California - Santa Barbara	Santa Barbara
CA	University of California - Santa Cruz	Santa Cruz
CA	University of Redlands	Redlands
CA	University of San Diego	San Diego
CA	University of San Francisco	San Francisco
CA	University of Southern California	Los Angeles
CA	University of the Pacific	Stockton
CA	West Valley College	Saratoga
CA	Westmont College	Santa Barbara
CA	Whittier College	Whittier
CA	Woodbury University	Burbank
CO	Colorado College	Colorado Springs
CO	Colorado School of Mines	Golden
CO	Colorado State University	Fort Collins
CO	Colorado State University - Pueblo	Pueblo
CO	Fort Lewis College	Durango
CO	Johnson & Wales University	Denver
CO	Metropolitan State College of Denver	Denver
CO	Regis University	Denver
CO	University of Colorado - Boulder	Boulder
CO	University of Colorado - Colorado Spring	Colorado Springs
CO	University of Colorado-Health Sciences Center	Denver
CO	University of Denver	Denver
CO	University of Northern Colorado	Greeley
CT	Central Connecticut State University	New Britain
CT	Connecticut College	New London
CT	Fairfield University	Fairfield
CT	Sacred Heart University	Fairfield
CT	Southern Connecticut State University	New Haven
CT	Trinity College	Hartford

State	Institution	City
CT	University of Connecticut	Storrs Mansfield
CT	University of Hartford	West Hartford
CT	University of New Haven	West Haven
CT	Wesleyan University	Middletown
CT	Western Connecticut State University	Danbury
CT	Yale University	New Haven
DC	American University	Washington
DC	Catholic University of America	Washington
DC	George Washington University	Washington
DC	Georgetown University	Washington
DC	Howard University	Washington
DE	Delaware State University	Dover
DE	University of Delaware	Newark
DE	Wesley College - Delaware	Dover
FL	Barry University	Miami Shores
FL	Bethune-Cookman College	Daytona Beach
FL	Eckerd College	Saint Petersburg
FL	Embry-Riddle Aeronautical University	Daytona Beach
FL	Florida Atlantic University	Boca Raton
FL	Florida Gulf Coast University	Fort Myers
FL	Florida International University	Miami
FL	Florida International University - North Miami Campus	North Miami
FL	Florida Southern College	Lakeland
FL	Florida State University	Tallahassee
FL	Indian River Community College	Fort Pierce
FL	Palm Beach Atlantic University	West Palm Beach
FL	Rollins College	Winter Park
FL	University of Central Florida	Orlando
FL	University of Florida - Gainesville	Gainesville
FL	University of Miami	Miami
FL	University of North Florida	Jacksonville
FL	University of South Florida - Sarasota - New College	Sarasota
FL	University of South Florida - Tampa	Tampa
FL	University of Tampa	Tampa
FL	University of West Florida	Pensacola
GA	Abraham Baldwin Agricultural College	Tifton
GA	Agnes Scott College	Decatur
GA	Albany State University	Albany
GA	Berry College	Mount Berry
GA	Clayton State University	Morrow
GA	Covenant College	Lookout Mountain
GA	Emory University	Atlanta
GA	Georgia College and State University	Milledgeville
GA	Georgia Institute of Technology	Atlanta
GA	Georgia Military College	Milledgeville
GA	Georgia Southern University	Statesboro

State	Institution	City
GA	Georgia Southwestern University	Americus
GA	Georgia State University	Atlanta
GA	Kennesaw State University	Kennesaw
GA	Macon State College	Macon
GA	Medical College of Georgia	Augusta
GA	Mercer University	Macon
GA	Morehouse School of Medicine	Atlanta
GA	North Georgia College and State University	Dahlonega
GA	Oxford College - Emory University	Oxford
GA	Reinhardt College	Waleska
GA	Savannah College of Art & Design	Savannah
GA	Shorter College	Rome
GA	Southern Catholic College	Dawsonville
GA	Spelman College	Atlanta
GA	University of Georgia	Athens
GA	University of West Georgia	Carrollton
GA	Valdosta State University	Valdosta
GA	Young Harris College	Young Harris
HI	University of Hawaii - Manoa	Honolulu
IA	Briar Cliff College	Sioux City
IA	Buena Vista University	Storm Lake
IA	Central College	Pella
IA	Clarke College	Dubuque
IA	Coe College	Cedar Rapids
IA	Cornell College	Mount Vernon
IA	Dordt College	Sioux Center
IA	Drake University	Des Moines
IA	Graceland University	Lamoni
IA	Grinnell College	Grinnell
IA	Iowa State University	Ames
IA	Kirkwood Community College	Cedar Rapids
IA	Loras College	Dubuque
IA	Luther College	Decorah
IA	Morningside College	Sioux City
IA	Mount Mercy College	Cedar Rapids
IA	Northwestern College	Orange City
IA	University of Iowa	Iowa City
IA	University of Northern Iowa	Cedar Falls
IA	Wartburg College	Waverly
ID	Albertson College of Idaho	Caldwell
ID	Boise State University	Boise
ID	Idaho State University	Pocatello
ID	Northwest Nazarene University	Nampa
ID	University of Idaho	Moscow
IL	Aurora University	Aurora
IL	Benedictine University	Lisle

State	Institution	City
IL	Bradley University	Peoria
IL	Chicago State University	Chicago
IL	College of Lake County	Grayslake
IL	Dominican University	River Forest
IL	Eastern Illinois University	Charleston
IL	Elmhurst College	Elmhurst
IL	Illinois Central College	Peoria
IL	Illinois College	Jacksonville
IL	Illinois College of Optometry	Chicago
IL	Illinois State University	Normal
IL	Lake Forest College	Lake Forest
IL	Lewis University	Romeoville
IL	Lincoln College	Lincoln
IL	Loyola University - Chicago	Chicago
IL	McKendree College	Lebanon
IL	Moody Bible Institute	Chicago
IL	North Park University	Chicago
IL	Northeastern Illinois University	Chicago
IL	Northern Illinois University	DeKalb
IL	Northwestern University	Evanston
IL	Oakton Community College	Des Plaines
IL	Olivet Nazarene University	Bourbonnais
IL	Rockford College	Rockford
IL	Saint Francis Medical Center	Peoria
IL	Saint Xavier University	Chicago
IL	School of the Art Institute	Chicago
IL	Southern Illinois University - Carbondale	Carbondale
IL	Southern Illinois University - Edwardsville	Edwardsville
IL	Triton College	River Grove
IL	University of Chicago Hospitals	Chicago
IL	University of Illinois - Chicago	Chicago
IL	University of Illinois - Springfield	Springfield
IL	University of Illinois at Urbana - Champaign	Urbana
IL	University of Saint Francis	Joliet
IL	Western Illinois University	Macomb
IL	Wheaton College - Illinois	Wheaton
IL	William Rainey Harper College	Palatine
IN	Ball State University	Muncie
IN	Bethel College - Indiana	Mishawaka
IN	Butler University	Indianapolis
IN	DePauw University	Greencastle
IN	Earlham College	Richmond
IN	Goshen College	Goshen
IN	Grace College and Seminary	Winona Lake
IN	Hanover College	Hanover
IN	Indiana State University	Terre Haute

State	Institution	City
IN	Indiana University - Purdue University Fort Wayne	Fort Wayne
IN	Indiana University - South Bend	South Bend
IN	Martin University	Indianapolis
IN	Saint Mary's College	Notre Dame
IN	Taylor University	Upland
IN	Valparaiso University	Valparaiso
IN	Wabash College	Crawfordsville
KS	Baker University	Baldwin City
KS	Butler County Community College	El Dorado
KS	Cowley College	Arkansas City
KS	Emporia State University	Emporia
KS	Fort Hays State University	Hays
KS	Garden City Community College	Garden City
KS	Kansas City Kansas Community College	Kansas City
KS	Kansas State University	Manhattan
KS	MidAmerica Nazarene University	Olathe
KS	Ottawa University	Ottawa
KS	Pittsburg State University	Pittsburg
KS	Pratt Community College	Pratt
KS	University of Kansas	Lawrence
KS	University of Saint Mary	Leavenworth
KS	Washburn University	Topeka
KS	Wichita State University	Wichita
KY	Asbury College	Wilmore
KY	Berea College	Berea
KY	Centre College	Danville
KY	Eastern Kentucky University	Richmond
KY	Morehead State University	Morehead
KY	Murray State University	Murray
KY	Northern Kentucky University	Highland Heights
KY	University of Kentucky	Lexington
KY	University of Louisville	Louisville
KY	University of Louisville - Belknap Campus	Louisville
KY	Western Kentucky University	Bowling Green
LA	Delgado Community College	New Orleans
LA	Dillard University	New Orleans
LA	Grambling State University	Grambling
LA	Louisiana State University	Baton Rouge
LA	Louisiana Tech University	Ruston
LA	Loyola University - New Orleans	New Orleans
LA	Nicholls State University	Thibodaux
LA	Northwestern State University	Natchitoches
LA	Our Lady of Holy Cross College	New Orleans
LA	Our Lady of the Lake College	Baton Rouge
LA	Southeastern Louisiana University	Hammond
LA	Tulane University	New Orleans

State	Institution	City
LA	University of Louisiana - Lafayette	Lafayette
LA	University of Louisiana - Monroe	Monroe
LA	University of New Orleans - Lakefront	New Orleans
LA	Xavier University	New Orleans
MA	Amherst College	Amherst
MA	Anna Maria College	Paxton
MA	Assumption College	Worcester
MA	Babson College	Babson Park
MA	Bentley College	Waltham
MA	Boston Conservatory	Boston
MA	Brandeis University	Waltham
MA	Bridgewater State College	Bridgewater
MA	Bristol Community College	Fall River
MA	Clark University	Worcester
MA	College of the Holy Cross	Worcester
MA	Eastern Nazarene College	Quincy
MA	Emerson College	Boston
MA	Fitchburg State College	Fitchburg
MA	Framingham State College	Framingham
MA	Harvard University	Cambridge
MA	Lesley University	Malden
MA	Massachusetts College of Art	Boston
MA	Massachusetts Institute of Technology	Cambridge
MA	Massachusetts Maritime Academy	Buzzards Bay
MA	Middlesex Community College	Lowell
MA	Mount Holyoke College	South Hadley
MA	Mount Ida College	Newton
MA	Nichols College	Dudley
MA	Northeastern University	Boston
MA	Pine Manor College	Chestnut Hill
MA	Regis College	Weston
MA	Salem State College	Salem
MA	Simmons College	Boston
MA	Simon's Rock College of Bard	Great Barrington
MA	Smith College	Northampton
MA	Springfield College	Springfield
MA	Stonehill College	North Easton
MA	Suffolk University	Boston
MA	Tufts University	Medford
MA	University of Massachusetts - Amherst	Amherst
MA	University of Massachusetts - Boston	Boston
MA	University of Massachusetts - Dartsmouth	North Dartmouth
MA	University of Massachusetts - Lowell	Lowell
MA	Wellesley College	Wellesley
MA	Western New England College	Springfield
MA	Westfield State College	Westfield

State	Institution	City
MA	Wheaton College - Massachusetts	Norton
MA	Williams College	Williamstown
MA	Worcester State College	Worcester
MD	Anne Arundel Community College	Arnold
MD	Bowie State University	Bowie
MD	Coppin State University	Baltimore
MD	Frostburg State University	Frostburg
MD	Goucher College	Towson
MD	Hood College	Frederick
MD	Johns Hopkins University	Baltimore
MD	Loyola College	Baltimore
MD	Maryland Institute College of Art	Baltimore
MD	McDaniel College	Westminster
MD	Morgan State University	Baltimore
MD	Mount Saint Mary's University	Emmitsburg
MD	Saint Mary's College of Maryland	Saint Mary's City
MD	Salisbury University	Salisbury
MD	Towson University	Baltimore
MD	University of Maryland - Baltimore County	Baltimore
MD	University of Maryland - College Park	College Park
MD	University of Maryland - Eastern Shore	Princess Anne
MD	Villa Julie College	Stevenson
MD	Washington College	Chestertown
ME	Unity College	Unity
ME	University of Maine - Farmington	Farmington
ME	University of Southern Maine	Portland
MI	Adrian College	Adrian
MI	Albion College	Albion
MI	Alma College	Alma
MI	Aquinas College	Grand Rapids
MI	Calvin College	Grand Rapids
MI	Central Michigan University	Mount Pleasant
MI	Charles S. Mott Community College	Flint
MI	Cornerstone University	Grand Rapids
MI	Eastern Michigan University	Ypsilanti
MI	Ferris State University	Big Rapids
MI	Hope College	Holland
MI	Kalamazoo College	Kalamazoo
MI	Kettering University	Flint
MI	Lake Superior State University	Sault Sainte Marie
MI	Michigan State University	East Lansing
MI	Oakland University	Rochester
MI	Olivet College	Olivet
MI	Saginaw Valley State University	University Center
MI	Siena Heights University	Adrian
MI	Spring Arbor University	Spring Arbor

State	Institution	City
MI	University of Detroit - Mercy	Detroit
MI	University of Michigan	Ann Arbor
MI	University of Michigan - Flint	Flint
MI	Western Michigan University	Kalamazoo
MN	Augsburg College	Saint Paul
MN	Bemidji State University	Bemidji
MN	Bethel University	Saint Paul
MN	Carleton College	Northfield
MN	College of Saint Benedict	Collegeville
MN	College of Saint Catherine	Saint Paul
MN	College of Saint Scholastica	Duluth
MN	Crown College	Saint Bonifacius
MN	Gustavus Adolphus College	Saint Peter
MN	Lake Superior College	Duluth
MN	Macalester College	Saint Paul
MN	Minnesota State University - Mankato	Mankato
MN	Minnesota State University - Moorhead	Moorhead
MN	Northwestern College	Roseville
MN	Saint Cloud State University	Saint Cloud
MN	Saint Mary's University - Minnesota	Winona
MN	Southwest State University	Marshall
MN	University of Minnesota - Duluth	Duluth
MN	University of Minnesota - Minneapolis	Minneapolis
MN	University of Saint Thomas	Saint Paul
MN	Winona State University	Winona
MO	Central Missouri State University	Warrensburg
MO	Culver-Stockton College	Canton
MO	Drury University	Springfield
MO	Kansas City Art Institute	Kansas City
MO	Lincoln University	Jefferson City
MO	Missouri Southern State University	Joplin
MO	Missouri Western State University	Saint Joseph
MO	Northwest Missouri State University	Maryville
MO	Rockhurst University	Kansas City
MO	Saint Louis Community College - Forest Park Campus	Saint Louis
MO	Saint Louis Community College - Forest Park Campus	Saint Louis
MO	Saint Louis Community College - Meramec	Saint Louis
MO	Southeast Missouri State University	Cape Girardeau
MO	Truman State University	Kirksville
MO	University of Missouri - Columbia	Columbia
MO	University of Missouri - Kansas City	Kansas City
MO	University of Missouri - Rolla	Rolla
MO	University of Missouri - Saint Louis	Saint Louis
MO	Washington University in Saint Louis	Saint Louis
MO	Webster University	Saint Louis
MO	Westminster College - Missouri	Fulton

State	Institution	City
MO	William Woods University	Fulton
MS	Alcorn State University	Lorman
MS	Jackson State University	Jackson
MS	Mississippi State University	Mississippi State
MS	Mississippi University for Women	Columbus
MS	Tougaloo College	Tougaloo
MS	University of Mississippi	University
MS	University of Southern Mississippi	Hattiesburg
MT	Montana State University - Billings	Billings
MT	Montana State University - Bozeman	Bozeman
MT	Montana State University - Northern	Havre
MT	University of Montana	Missoula
NC	Appalachian State University	Boone
NC	Barton College	Wilson
NC	Brevard College	Brevard
NC	Catawba College	Salisbury
NC	Davidson College	Davidson
NC	Duke University	Durham
NC	East Carolina University	Greenville
NC	Elon University	Elon
NC	Greensboro College	Greensboro
NC	Guilford College	Greensboro
NC	Johnson & Wales University - Charlotte Campus	Charlotte
NC	Lenoir - Rhyne College	Hickory
NC	Mars Hill College	Mars Hill
NC	Meredith College	Raleigh
NC	Mount Olive College	Mount Olive
NC	North Carolina Agricultural & Technical State University	Greensboro
NC	North Carolina Central University	Durham
NC	North Carolina School of the Arts	Winston Salem
NC	North Carolina State University	Raleigh
NC	Peace College	Raleigh
NC	Salem College	Winston Salem
NC	University of North Carolina - Asheville	Asheville
NC	University of North Carolina - Chapel Hill	Chapel Hill
NC	University of North Carolina - Charlotte	Charlotte
NC	University of North Carolina - Greensboro	Greensboro
NC	University of North Carolina - Pembroke	Pembroke
NC	University of North Carolina - Wilmington	Wilmington
NC	Wake Forest University	Winston Salem
NC	Western Carolina University	Cullowhee
NC	Winston-Salem State University	Winston Salem
ND	Dickinson State University	Dickinson
ND	Minot State University	Minot
ND	North Dakota State University	Fargo

State	Institution	City
ND	University of North Dakota	Grand Forks
NE	Chadron State College	Chadron
NE	Concordia University - Nebraska	Seward
NE	Creighton University	Omaha
NE	Dana College	Blair
NE	Doane College	Crete
NE	Hastings College	Hastings
NE	Midland Lutheran College	Fremont
NE	Nebraska Wesleyan University	Lincoln
NE	University of Nebraska - Kearney	Kearney
NE	University of Nebraska - Lincoln	Lincoln
NE	University of Nebraska - Omaha	Omaha
NE	Wayne State College	Wayne
NH	Colby-Sawyer College	New London
NH	Daniel Webster College	Nashua
NH	Dartmouth College	Hanover
NH	Franklin Pierce College	Rindge
NH	Keene State College	Keene
NH	New England College	Henniker
NH	New Hampshire Technical Institute	Concord
NH	Plymouth State University	Plymouth
NH	Rivier College	Nashua
NH	Saint Anselm College	Manchester
NH	University of New Hampshire	Durham
NJ	Bergen Community College	Paramus
NJ	Bloomfield College	Bloomfield
NJ	Brookdale Community College	Lincroft
NJ	College of Saint Elizabeth	Morristown
NJ	Drew University	Madison
NJ	Fairleigh Dickinson University - Metropolitan Campus	Teaneck
NJ	Felician College	Rutherford
NJ	Georgian Court University	Lakewood
NJ	Gloucester County College	Sewell
NJ	Kean University	Union
NJ	Middlesex County College	Edison
NJ	Montclair State University	Upper Montclair
NJ	New Jersey City University	Jersey City
NJ	New Jersey Institute of Technology	Newark
NJ	Ocean County College	Toms River
NJ	Princeton University	Princeton
NJ	Ramapo College of New Jersey	Mahwah
NJ	Richard Stockton College of New Jersey	Pomona
NJ	Rowan University	Glassboro
NJ	Rutgers University	New Brunswick
NJ	Rutgers University - Newark	Newark
NJ	Stevens Institute of Technology	Hoboken

State	Institution	City
NJ	The College of New Jersey	Ewing
NJ	William Paterson University	Wayne
NM	New Mexico Institute of Mining and Technology	Socorro
NM	New Mexico State University	Las Cruces
NM	Saint John's College - Santa Fe	Santa Fe
NM	University of New Mexico	Albuquerque
NV	University of Nevada - Las Vegas	Las Vegas
NV	University of Nevada - Reno	Reno
NY	Alfred University	Alfred
NY	American University of Beirut	New York
NY	Bard College	Annandale On Hudson
NY	Broome Community College	Binghamton
NY	Buffalo State College	Buffalo
NY	Canisius College	Buffalo
NY	Cayuga Community College	Auburn
NY	Cazenovia College	Cazenovia
NY	City University of New York - Brooklyn College	Brooklyn
NY	City University of New York - Central Office	New York
NY	City University of New York - Hunter College	New York
NY	City University of New York - Lehman College	Bronx
NY	City University of New York - New York City	Brooklyn
NY	City University of New York - Queens College	Flushing
NY	Colgate University	Hamilton
NY	College of New Rochelle	New Rochelle
NY	Columbia University	New York
NY	Columbia-Greene Community College	Hudson
NY	Cornell University	Ithaca
NY	Crouse Hospital School of Nursing	Syracuse
NY	Davis College	Johnson City
NY	Dominican College of Blauvelt	Orangeburg
NY	Dutchess Community College	Poughkeepsie
NY	Elmira College	Elmira
NY	Finger Lakes Community College	Canandaigua
NY	Fordham University	Bronx
NY	Hamilton College	Clinton
NY	Hartwick College	Oneonta
NY	Hobart & William Smith Colleges	Geneva
NY	Hofstra University	Hempstead
NY	Houghton College	Houghton
NY	Hudson Valley Community College	Troy
NY	Iona College	New Rochelle
NY	Ithaca College	Ithaca
NY	Keuka College	Keuka Park
NY	LeMoyne College	Syracuse
NY	Manhattanville College	Purchase

State	Institution	City
NY	Nassau Community College	Garden City
NY	Nazareth College of Rochester	Rochester
NY	New York University	New York
NY	Niagara University	Niagara University
NY	North Country Community College	Saranac Lake
NY	Nyack College	Nyack
NY	Pace University	Pleasantville
NY	Pratt Institute	Brooklyn
NY	Rensselaer Polytechnic Institute	Troy
NY	Rochester Institute of Technology	Rochester
NY	Sage College	Albany
NY	Saint John Fisher College	Rochester
NY	Saint John's University - New York	Queens
NY	Saint John's University - Staten Island	Staten Island
NY	Saint Lawrence University	Canton
NY	School of Visual Arts	New York
NY	Siena College	Loudonville
NY	Skidmore College	Saratoga Springs
NY	State University of New York - Albany	Albany
NY	State University of New York - Brockport	Brockport
NY	State University of New York - Buffalo	Buffalo
NY	State University of New York - Canton	Canton
NY	State University of New York - Cobleskill	Cobleskill
NY	State University of New York - Cortland	Cortland
NY	State University of New York - Geneseo	Geneseo
NY	State University of New York - New Paltz College	New Paltz
NY	State University of New York - Oneonta	Oneonta
NY	State University of New York - Oswego	Oswego
NY	State University of New York - Purchase	Purchase
NY	State University of New York - Plattsburgh	Plattsburgh
NY	State University of New York - Potsdam	Potsdam
NY	Stony Brook University	Stony Brook
NY	Suffolk County Community College	Riverhead
NY	Syracuse University	Syracuse
NY	The New School University	New York
NY	Tomkins Cortland Community College	Dryden
NY	Union College	Schenectady
NY	University of Rochester	Rochester
NY	Vassar College	Poughkeepsie
NY	Wagner College	Staten Island
NY	Wells College	Aurora
OH	Ashland University	Ashland
OH	Baldwin-Wallace College	Berea
OH	Bowling Green State University	Bowling Green
OH	Capital University	Columbus
OH	Case Western Reserve University	Cleveland

State	Institution	City
OH	Cedarville University	Cedarville
OH	Central State University	Wilberforce
OH	Cleveland State University	Cleveland
OH	College of Mount Saint Joseph	Cincinnati
OH	College of Wooster	Wooster
OH	Denison University	Granville
OH	Edison Community College	Piqua
OH	Franciscan University	Steubenville
OH	Hiram College	Hiram
OH	Hocking College	Nelsonville
OH	John Carroll University	University Heights
OH	Kent State University	Kent
OH	Kenyon College	Gambier
OH	Lorain County Community College	Elyria
OH	Miami University - Ohio	Oxford
OH	Mount Carmel College of Nursing	Columbus
OH	Mount Union College	Alliance
OH	Oberlin College	Oberlin
OH	Ohio Northern University	Ada
OH	Ohio State University	Columbus
OH	University of Akron	Akron
OH	University of Rio Grande	Rio Grande
OH	University of Toledo	Toledo
OH	Wright State University	Dayton
OK	Oklahoma Panhandle State University	Goodwell
OK	Oklahoma State University - Okmulgee	Okmulgee
OK	Oklahoma State University - Stillwater	Stillwater
OK	Rogers State University	Claremore
OK	Southeastern Oklahoma State University	Durant
OK	Southern Nazarene University	Bethany
OK	University of Central Oklahoma	Edmond
OK	University of Oklahoma	Norman
OK	University of Tulsa	Tulsa
OR	Eastern Oregon University	La Grande
OR	George Fox University	Newberg
OR	Lewis & Clark College	Portland
OR	Mount Hood Community College	Gresham
OR	Oregon Health & Science University	Portland
OR	Oregon Institute of Technology	Klamath Falls
OR	Oregon State University	Corvallis
OR	Pacific University	Forest Grove
OR	Portland State University	Portland
OR	Reed College	Portland
OR	Southern Oregon University	Ashland
OR	University of Oregon	Eugene
OR	University of Portland	Portland

State	Institution	City
OR	Western Oregon University	Monmouth
OR	Willamette University	Salem
PA	Albright College	Reading
PA	Allegheny College	Meadville
PA	Alvernia College	Reading
PA	Arcadia University	Glenside
PA	Bloomsburg University	Bloomsburg
PA	Bryn Mawr College	Bryn Mawr
PA	Bucknell University	Lewisburg
PA	California University of Pennsylvania	California
PA	Carnegie Mellon University	Pittsburgh
PA	Chestnut Hill College	Philadelphia
PA	Clarion University of Pennsylvania	Clarion
PA	Delaware Valley College	Doylestown
PA	DeSales University	Center Valley
PA	Dickinson College	Carlisle
PA	Duquesne University	Pittsburgh
PA	East Stroudsburg University	East Stroudsburg
PA	Eastern College	Saint Davids
PA	Edinboro University of Pennsylvania	Edinboro
PA	Elizabethtown College	Elizabethtown
PA	Franklin and Marshall College	Lancaster
PA	Gettysburg College	Gettysburg
PA	Haverford College	Haverford
PA	Holy Family University	Philadelphia
PA	Immaculata University	Immaculata
PA	Indiana University of Pennsylvania	Indiana
PA	Keystone College	La Plume
PA	King's College	Wilkes Barre
PA	Kutztown University	Kutztown
PA	Lafayette College	Easton
PA	LaSalle University	Philadelphia
PA	Lebanon Valley College	Annville
PA	Lehigh University	Bethlehem
PA	Lincoln University	Lincoln University
PA	Lycoming College	Williamsport
PA	Marywood University	Scranton
PA	Messiah College	Grantham
PA	Millersville University	Millersville
PA	Moravian College	Bethlehem
PA	Mount Aloysius College	Cresson
PA	Muhlenberg College	Allentown
PA	Northampton Community College	Bethlehem
PA	Pennsylvania College of Technology	Williamsport
PA	Pennsylvania State University	University Park
PA	Pennsylvania State University - Altoona	Altoona

State	Institution	City
PA	Pennsylvania State University - Dubois	DuBois
PA	Philadelphia Biblical University	Langhorne
PA	Philadelphia University	Philadelphia
PA	Point Park College	Pittsburgh
PA	Robert Morris University	Moon Township
PA	Rosemont College	Rosemont
PA	Saint Francis University	Loretto
PA	Saint Joseph's University	Philadelphia
PA	Seton Hill University	Greensburg
PA	Shippensburg University	Shippensburg
PA	Slippery Rock University	Slippery Rock
PA	Susquehanna University	Selinsgrove
PA	Swarthmore College	Swarthmore
PA	Temple University	Philadelphia
PA	The Williamson Free School of Mechanical Trades	Media
PA	Thiel College	Greenville
PA	University of Pennsylvania	Philadelphia
PA	University of Pittsburgh	Pittsburgh
PA	University of Pittsburgh - Bradford	Bradford
PA	University of Pittsburgh - Greensburg	Greensburg
PA	University of Pittsburgh - Johnstown	Johnstown
PA	University of Scranton	Scranton
PA	University of the Arts	Philadelphia
PA	University of the Sciences in Philadelphia	Philadelphia
PA	Ursinus College	Collegeville
PA	Valley Forge Christian College	Phoenixville
PA	Villanova University	Villanova
PA	Washington & Jefferson College	Washington
PA	West Chester University	West Chester
PA	Westminster College - Pennsylvania	New Wilmington
PA	Widener University - Pennsylvania	Chester
PA	Wilkes University	Wilkes Barre
PA	Wilson College	Chambersburg
PA	York College of Pennsylvania	York
RI	Bryant University	Smithfield
RI	Providence College	Providence
RI	Rhode Island College	Providence
RI	Roger Williams University	Bristol
RI	Salve Regina University	Newport
RI	University of Rhode Island	Kingston
SC	Anderson University	Anderson
SC	Benedict College	Columbia
SC	Clemson University	Clemson
SC	Coastal Carolina University	Conway
SC	College of Charleston	Charleston
SC	Columbia College	Columbia

State	Institution	City
SC	Converse College	Spartanburg
SC	Francis Marion University	Florence
SC	Furman University	Greenville
SC	Lander University	Greenwood
SC	Medical University of South Carolina	Charleston
SC	South Carolina State University	Orangeburg
SC	University of South Carolina - Aiken	Aiken
SC	University of South Carolina - Columbia	Columbia
SC	University of South Carolina - Upstate	Spartanburg
SC	Winthrop University	Rock Hill
SD	Augustana College	Sioux Falls
SD	Black Hills State University	Spearfish
SD	South Dakota State University	Brookings
SD	University of South Dakota	Vermillion
TN	Austin Peay State University	Clarksville
TN	Belmont University	Nashville
TN	East Tennessee State University	Johnson City
TN	Lambuth University	Jackson
TN	Lipscomb University	Nashville
TN	Maryville College	Maryville
TN	Middle Tennessee State University	Murfreesboro
TN	Northeast State Tech Community College	Blountville
TN	Rhodes College	Memphis
TN	Southern Adventist University	Collegedale
TN	Tennessee State University	Nashville
TN	Tennessee Technological University	Cookeville
TN	University of Tennessee - Knoxville	Knoxville
TN	University of Tennessee - Martin	Martin
TN	University of Tennessee - Memphis	Memphis
TN	University of the South	Sewanee
TN	Vanderbilt University	Nashville
TN	Walters State Community College	Morristown
TX	Abilene Christian University	Abilene
TX	Angelo State University	San Angelo
TX	Austin College	Sherman
TX	Baylor University	Waco
TX	Brookhaven College	Farmers Branch
TX	Cedar Valley College	Lancaster
TX	Eastfield College	Mesquite
TX	El Centro College	Dallas
TX	Hardin-Simmons University	Abilene
TX	Lamar University	Beaumont
TX	Midwestern State University	Wichita Falls
TX	Mountain View College	Dallas
TX	North Lake College	Irving
TX	Palo Alto College	San Antonio

State	Institution	City
TX	Prairie View A & M University	Prairie View
TX	Rice University	Houston
TX	Richland College	Dallas
TX	Saint Edward's University	Austin
TX	Saint Mary's University - Texas	San Antonio
TX	Saint Philip's College	San Antonio
TX	Sam Houston State University	Huntsville
TX	San Antonio College	San Antonio
TX	Schreiner University	Kerrville
TX	Southern Methodist University	Dallas
TX	Tarleton State University	Stephenville
TX	Tarrant County College - Northeast Campus	Hurst
TX	Tarrant County College - South Campus	Fort Worth
TX	Texas A & M International University Laredo	Laredo
TX	Texas A & M University - College Station	College Station
TX	Texas A & M University - Commerce	Commerce
TX	Texas A & M University - Corpus Christi	Corpus Christi
TX	Texas A & M University - Galveston	Galveston
TX	Texas A & M University - Kingsville	Kingsville
TX	Texas Christian University	Fort Worth
TX	Texas Lutheran University	Seguin
TX	Texas Southern University	Houston
TX	Texas State Technical College - West Texas	Sweetwater
TX	Texas State University - San Marcos	San Marcos
TX	Texas Tech University	Lubbock
TX	Texas Woman's University	Denton
TX	Trinity University	San Antonio
TX	University of Mary Hardin-Baylor	Belton
TX	University of North Texas	Denton
TX	University of Saint Thomas - Houston	Houston
TX	University of Texas - Arlington	Arlington
TX	University of Texas - Austin	Austin
TX	University of Texas - Brownsville	Brownsville
TX	University of Texas - Dallas	Richardson
TX	University of Texas - El Paso	El Paso
TX	University of Texas - Medical Branch	Galveston
TX	University of Texas - Pan American	Edinburg
TX	University of Texas - San Antonio	San Antonio
TX	University of Texas - Tyler	Tyler
TX	University of the Incarnate Word	San Antonio
UT	University of Utah	Salt Lake City
UT	Utah State University	Logan
UT	Utah Valley State College	Orem
UT	Weber State University	Ogden
VA	Christopher Newport University	Newport News
VA	College of William & Mary	Williamsburg

State	Institution	City
VA	Eastern Mennonite University	Harrisonburg
VA	Emory and Henry College	Emory
VA	Ferrum College	Ferrum
VA	George Mason University	Fairfax
VA	Hampden-Sydney College	Hampden Sydney
VA	Hampton University	Hampton
VA	Hollins University	Roanoke
VA	James Madison University	Harrisonburg
VA	Longwood University	Farmville
VA	Lynchburg College	Lynchburg
VA	Marymount University	Arlington
VA	Northern Virginia Community College	Springfield
VA	Old Dominion University	Norfolk
VA	Radford University	Radford
VA	Randolph - Macon Woman's College	Lynchburg
VA	Roanoke College	Salem
VA	Shenandoah University	Winchester
VA	University of Mary Washington	Fredericksburg
VA	University of Richmond	Richmond
VA	University of Virginia	Charlottesville
VA	Virginia Commonwealth University	Richmond
VA	Virginia State University	Petersburg
VA	Virginia Tech	Blacksburg
VA	Virginia Wesleyan College	Norfolk
VA	Washington & Lee University	Lexington
VI	University of the Virgin Islands	Saint Thomas
VT	Bennington College	Bennington
VT	Castleton State College	Castleton
VT	Champlain College	Burlington
VT	Landmark College	Putney
VT	Marlboro College	Marlboro
VT	Middlebury College	Middlebury
VT	Norwich University	Northfield
VT	Saint Michael's College	Colchester
VT	Vermont Technical College	Randolph Center
WA	Central Washington University	Ellensburg
WA	Eastern Washington University	Cheney
WA	Evergreen State College	Olympia
WA	Gonzaga University	Spokane
WA	Seattle University	Seattle
WA	University of Puget Sound	Tacoma
WA	Walla Walla University	College Place
WA	Washington State University	Pullman
WA	Whitman College	Walla Walla
WI	Alverno College	Milwaukee
WI	Beloit College	Beloit

State	Institution	City
WI	Carroll College - Wisconsin	Waukesha
WI	Edgewood College	Madison
WI	Lawrence University	Appleton
WI	Marquette University	Milwaukee
WI	Milwaukee School of Engineering	Milwaukee
WI	Mount Mary College	Milwaukee
WI	Northland College	Ashland
WI	Saint Norbert College	DePere
WI	University of Wisconsin - Green Bay	Green Bay
WI	University of Wisconsin - La Crosse	La Crosse
WI	University of Wisconsin - Madison	Madison
WI	University of Wisconsin - Milwaukee	Milwaukee
WI	University of Wisconsin - Oshkosh	Oshkosh
WI	University of Wisconsin - Parkside	Kenosha
WI	University of Wisconsin - Platteville	Platteville
WI	University of Wisconsin - River Falls	River Falls
WI	University of Wisconsin - Stevens Point	Stevens Point
WI	University of Wisconsin - Stout	Menomonie
WI	University of Wisconsin - Whitewater	Whitewater
WI	Viterbo University	La Crosse
WV	Fairmont State College - Clarksburg	Fairmont
WV	Glenville State College	Glenville
WV	Marshall University	Huntington
WV	Potomac State College of West Virginia University	Keyser
WV	Shepherd University	Shepherdstown
WV	West Liberty State College	West Liberty
WV	West Virginia University	Morgantown
WV	West Virginia Wesleyan College	Buckhannon
WV	Wheeling Jesuit University	Wheeling
WY	Laramie County Community College	Cheyenne
WY	University of Wyoming	Laramie