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HEARING ON
OVERSIGHT AND ADMINISTRATION OF THE
340B DRUG DISCOUNT PROGRAM:
IMPROVING EFFICIENCY AND TRANSPARENCY

BEFORE THE
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
UNITED STATES HOUSE OF REPRESENTATIVES
2322 RAYBURN HOUSE OFFICE BUILDING

DECEMBER 15, 2005
1 P.M.

SUMMARY OF TESTIMONY

**BILL VON OEHSEN
GENERAL COUNSEL
PUBLIC HOSPITAL PHARMACY COALITION
BEFORE THE HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS**

**OVERSIGHT AND ADMINISTRATION OF THE 340B DRUG DISCOUNT
PROGRAM: IMPROVING EFFICIENCY AND TRANSPARENCY**

DECEMBER 15, 2005

The Public Hospital Pharmacy Coalition (PHPC)—an organization that represents approximately 330 disproportionate share hospitals (DSH) participating in the 340B drug discount program—is fundamentally in agreement with the recommendations of the Department of Health and Human Services (HHS) Office of Inspector General (OIG) in its recent report entitled “Deficiencies in the Oversight of the 340B Drug Pricing Program.” However, PHPC believes that there are a number of more specific and, in some instances, supplementary measures that should be implemented as soon as practicable to achieve truly responsible and effective administration of the program.

PHPC applauds the OIG for identifying the three most critical elements of necessary reform to the 340B program as it is currently administered by the Health Resources and Services Administration (HRSA). These three elements are: (1) establishment of a precisely defined methodology for determination of correct 340B ceiling prices, combined with a process for routinely making direct comparisons between the 340B ceiling prices calculated by HRSA and the ceiling prices calculated and charged by manufacturers for the same products; (2) authority for HRSA to impose meaningful sanctions on manufacturers in the form of fines and monetary penalties for charging covered entities above the 340B ceiling price or other violations of the 340B pharmaceutical pricing agreement (PPA); and (3) increased access by 340B entities to information enabling them to determine whether the prices they are being charged under the program are within the applicable statutory ceilings.

There are also several other problems in 340B program administration that are not covered in the OIG’s most recent report and which are of continuing concern to the 340B community notwithstanding the hard work by responsible federal officials to administer this important program. These include: (1) undue delay in the execution or limitation on the scope of 340B PPAs (2) the lack of a specific HRSA policy detailing the procedure by which manufacturers should issue refunds to covered entities whenever it is discovered or finally determined that they have sold 340B drugs at above-ceiling prices; (3) the difficulty that many 340B covered entities face in attempting to purchase drugs that are reportedly in short supply at the appropriate ceiling price; and (4) the absence of an effective administrative process for obtaining a binding and judicially reviewable resolution of claims by covered entities that manufacturers have charged prices for drugs that exceed the appropriate 340B ceiling price.

Good afternoon Mr. Chairman. I am Bill von Oehsen, General Counsel and founder of the Public Hospital Pharmacy Coalition (PHPC). Thank you for inviting me to share the views of PHPC and its member hospitals participating in the 340B drug discount program. As participants in the 340B program, PHPC's members have a deep interest in effective oversight of the 340B program and express our appreciation to your Subcommittee for holding this hearing. We also want to commend the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) in issuing its recent report outlining ways to improve administration of the program. PHPC supports all of the OIG's recommendations and, as explained in more detail below, would like to offer additional recommendations and comments. Before turning to those recommendations, however, I would like to say a few words about PHPC and the value of the 340B program to safety net institutions and their patients.

Background on PHPC

PHPC is a coalition of disproportionate share hospitals (DSH) established in 1993 by the National Association of Public Hospitals and Health Systems (NAPH) to represent NAPH members and other DSH hospitals with respect to the 340B drug discount program and other initiatives affecting the availability and cost of pharmaceutical care provided by our member hospitals. PHPC has had a longstanding and very constructive relationship with the office within the Health Resources and Services Administration (HRSA) charged with administering the 340B program, called the Office of Pharmacy Affairs (OPA), and with OPA's staff and director, whose cooperation, commitment to the program, and hard work is greatly appreciated by the 340B community. One of the fruits

of OPA's efforts is the prime vendor program which has generated deeper discounts and other value-added services for prime vendor participants, including many PHPC member hospitals.

PHPC's membership stands at approximately 330 hospitals and encompasses a wide range of institutions including both urban and rural hospitals; public and private non-profit hospitals; hospitals with bed sizes over 500, under 50 and in between; Catholic and other faith-based hospitals; academic medical centers; tertiary care hospitals with level one trauma centers, burn units and other specialized services; and community hospitals focused on more traditional acute care services. Notwithstanding such diversity, PHPC's members share a common mission of serving low income and uninsured patients, including significant numbers of the working poor. Indeed, it is because of their mission to serve the poor that PHPC's members all qualify for and participate in the 340B program. Hospital participation in the 340B program is limited to hospitals that receive Medicare DSH payment adjustments of 11.75 percent or higher, a standard that can only be satisfied if a high percent of the hospital's inpatient care is furnished, on a per day basis, to Medicaid recipients, low income Medicare beneficiaries, and/or other indigent individuals. 340B eligibility is also limited to hospitals that are owned or operated by state or local governments or have a contract with state or local governments to provide a significant level of indigent care (i.e. non-Medicare, non-Medicaid).

The subset of PHPC's membership which overlaps with NAPH's membership – approximately 100 hospitals – provides about 24 percent of all uncompensated hospital care in the U.S. even though it represents only two percent of all U.S. hospitals. Other

relevant characteristics from NAPH include the following. Over 55 percent of gross charges are related to patients on Medicaid or are uninsured. Twenty-one percent of all costs in NAPH-member hospitals are uncompensated compared to 5.5 percent of costs nationally. We suspect that PHPC's non-NAPH members have levels of uncompensated costs more comparable to NAPH members than to the national figures.

Value of the 340B Program

Access to discounts on outpatient drugs under the 340B program is vital to the ability of PHPC member hospitals to provide comprehensive pharmacy services to low income patients and other vulnerable populations. The role of pharmaceuticals in meeting the health care needs of individuals, especially those suffering from one or more chronic conditions, has grown significantly over the past two decades. It is therefore no exaggeration to say that access to affordable medications can make the difference between clinically appropriate and inappropriate care, and in some cases, life or death. I often hear from member hospitals that, but for the savings available on drugs bought through the 340B program, the hospitals could not afford to keep their outpatient pharmacies open or would have to limit pharmacy services by adopting strict formularies, higher co-pays or other utilization control measures.

For example, in a conversation last week with one of PHPC's longstanding members, the University of Kentucky Hospital, we were told that access to discounts under the 340B program is the "only reason" why the hospital can keep its outpatient pharmacy and chemotherapy clinic open. Shands Hospital at the University of Florida has a large

population of transplant patients who can live only with extensive pharmaceutical support. Many of these patients lack employer-based health insurance and there are gaps in coverage even for those patients that have some form of insurance. 340B pricing helps defray the cost of their post-operative medications, which enables them to resume productive lives. A couple of 340B hospitals in Milwaukee, Wisconsin – St. Joseph Regional Hospital and St. Michael’s Hospital – recently reported that they use the savings from the program to maintain a pharmacy assistance program for needy residents in the Milwaukee area and that one of the hospitals invested its 340B savings on Procrit to start a special anemia management clinic for renal disease patients. Every 340B provider – referred to as a “covered entity” in the statute – has a story like one of these attesting to the value of the 340B program.

Even with the savings available under the program, some hospitals still cannot meet the demand for low cost drugs by local residents who lack prescription drug coverage. Indeed, unless a 340B pharmacy has enough paying business to offset its losses in serving the uninsured, access to discounts under the 340B program is not enough to make ends meet. This is the primary reason why many eligible 340B covered entities, especially community health centers, do not even offer pharmacy services, let alone participate in the 340B program.

It is therefore critical that DSH hospitals and other covered entities participating in the 340B program receive the full discount on outpatient drugs to which they are entitled under federal law; and it is critical that the government agencies responsible for administering the program have the resources, authorities, and requisite systems in place

to assure that this occurs. Unfortunately, as the OIG report illustrates all too well, 340B providers can never be sure that they are receiving accurate pricing. Until such problems are resolved, the integrity of the 340B program remains compromised. PHPC asks Congress, HHS and HRSA to fix these problems; and in making this request I believe I am speaking for all 340B providers and the national organizations that represent them. Please note though, in making this request, we do not mean to imply that covered entities do not also have responsibilities for maintaining the integrity of the program. Covered entities have their own obligations under the law. In particular, 340B providers are prohibited from using the discounted drugs for anyone other than their own patients and are required to adjust their Medicaid purchasing and billing practices in order to protect manufacturers from giving 340B discounts and Medicaid rebates on the same drugs. PHPC takes these obligations very seriously and has been active in educating both members and non-members on how to comply with all aspects of the 340B program.

Comments on OIG Report

PHPC is fundamentally in agreement with the recommendations of the OIG in its recent report entitled “Deficiencies in the Oversight of the 340B Drug Pricing Program.” PHPC believes, however, that there are a number of more specific and, in some instances, supplementary measures that should be implemented as soon as practicable to achieve truly responsible and effective administration of the program. In my testimony here today, I would like both to address the importance of the OIG recommendations and to urge implementation of some of these other measures which, in our view, extend and supplement the findings and recommendations of the OIG.

PHPC applauds the OIG for identifying the three most critical elements of necessary reform to the 340B program as it is currently administered by HRSA. These three elements are: (1) establishment of a precisely defined methodology for determination of correct 340B ceiling prices, combined with a process for routinely making direct comparisons between the 340B ceiling prices calculated by HRSA and the ceiling prices calculated and charged by manufacturers for the same products; (2) authority for HRSA to impose meaningful sanctions on manufacturers in the form of fines and monetary penalties for charging covered entities in violation of the applicable 340B ceiling price or other violations of the 340B pharmaceutical pricing agreement (PPA); and (3) increased access by covered entities to information enabling them to determine whether the prices they are being charged for drugs under the program are within the applicable statutory ceilings. Importantly, in order to improve administration of the 340B program in these three areas, there must be better coordination between HRSA and the Centers for Medicare & Medicaid Services (CMS), especially the office within CMS responsible for administering the Medicaid rebate program.

Improved Coordination between HRSA and CMS

Both my testimony and the OIG's reported findings should serve to underscore the importance of improving communication between HRSA and CMS. There is a close statutory link between the 340B and Medicaid rebate programs. Although HRSA is responsible for administering the 340B program, it must rely on CMS to compile and provide the data necessary to calculate and verify correct 340B ceiling prices. Fraud or even routine computation errors identified in the Medicaid rebate context can signal

errors and overcharges in 340B pricing. There are other areas in which effective administration of the 340B program requires teamwork between HRSA and CMS. For example, the eligibility of a hospital to participate in the 340B program hinges upon its DSH payment adjustment percentage, which is calculated by CMS based on data maintained by CMS. Plus, the obligations of drug manufacturers to execute pharmaceutical pricing agreements (PPAs) with the Secretary of HHS and to participate in the 340B program are contingent on execution of Medicaid rebate agreements that are managed by CMS.

The OIG has identified a number of problems associated with computation and verification of 340B ceiling prices that are attributable to failures in communication or coordination between HRSA and CMS. These problems include CMS's omission of requisite data elements for 340B ceiling price computations and the agency's failure to adequately reconcile package size data necessary to calculate the ceiling prices. Accordingly, OIG has recommended that HRSA and CMS "work together to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices."

PHPC fully supports this recommendation, but also wants to point out that the need for coordination between HRSA and CMS is not limited to the area of sharing and calculating pricing data. Consequently, we feel that institution of a permanent working group to address and monitor all of the necessary interactions of HRSA and CMS in implementing the 340B program would substantially improve program administration and oversight. In addition to promoting coordination on matters of pricing data flow and

computation, a HRSA/CMS working group would be uniquely positioned: (1) to clarify procedures for determining whether a hospital's disproportionate share adjustment meets the 11.75 statutory threshold, (2) to develop mechanisms for protecting manufacturers from giving 340B discounts and Medicaid rebates on the same drug, and (3) to coordinate manufacturer refunds under the 340B and Medicaid rebate programs based on retroactive adjustments to a manufacturer's average manufacturer price (AMP) and best price.

For these and other reasons, formal establishment of a permanent HRSA/CMS working group would be an especially positive step towards the goal of those components "working together" as the OIG has recommended.

Pricing Computation and Verification

Turning now to the need for more concrete administrative reforms, perhaps the most glaring deficiency in 340B program administration identified by OIG is the fact that – in a program designed to impose price-limits on qualifying pharmaceutical sales – the responsible government agency has no system in place for establishing whether the limits have been properly applied or how exactly the price limits are to be calculated. It seems evident that, in order to verify manufacturer compliance with price ceiling requirements, HRSA (1) must determine exactly how, and on the basis of what data, 340B ceiling prices are to be computed, (2) must compute an accurate ceiling price for each covered drug available for purchase under 340B, and (3) must compare its ceiling price determinations with the prices computed and actually charged by drug manufacturers to verify that applicable price ceilings are not being exceeded. As the recent OIG report points out, the present lack of a precise, established methodology for calculating 340B

ceiling prices has led to inconsistencies in whether and how certain data elements are utilized in determining applicable 340B price ceilings, and has made it difficult or impossible to determine whether manufacturers have applied “correct” 340B pricing to their products. A specific, detailed methodology is needed but is lacking, for example, to standardize the time periods and package sizes used to calculate 340B ceiling prices. Clearly the first steps HRSA must make towards better fulfilling its responsibilities to oversee the 340B program are to establish a precise methodology by which 340B prices are to be calculated, and to calculate accurate prices for covered drugs using that methodology.

Accurate determinations of ceiling prices by itself will be of little utility, of course, if nothing is done to verify that the ceiling prices calculated independently by drug manufacturers are the same as those HRSA has determined to be accurate and applicable. As the new OIG report emphasizes, the absence of such comparisons is one of the systemic deficiencies in HRSA’s administration of the program that makes effective oversight of 340B pricing impossible. Especially since covered entities lack access to ceiling price information, and thus have no basis on which to independently challenge the accuracy of 340B prices charged by manufacturers, there is no effective way to identify and control overcharging in the 340B program unless HRSA takes affirmative steps to verify that the ceiling prices it calculates are the same prices actually applied to purchases under the program.

Comparisons between the government-calculated 340B ceiling prices and manufacturers’ ceiling price figures should therefore be made on a routine basis, and should trigger

further specific procedures for inquiry and corrective action where discrepancies are found. OIG has suggested that this could be accomplished by requesting manufacturers to submit some or all 340B prices to HRSA each quarter. PHPC believes that HRSA should not merely request, but should require manufacturers to submit all of the 340B ceiling prices that they have calculated to HRSA each quarter for verification of pricing accuracy. In addition, as the OIG has recommended, HRSA should not only verify consistency between its calculations of 340B ceiling prices and those calculated by manufacturers, but also perform sufficient spot-checking of entity invoices to confirm that actual charges are indeed at or below the properly calculated ceiling prices.

Need for Meaningful Sanctions

The improved monitoring of 340B pricing that is achievable by the above reforms will not lead to more accurate pricing, however, without more effective incentives for manufacturers to comply with pricing requirements and directives from HRSA to remedy pricing violations that may be discovered. As matters now stand, a manufacturer whose product has been determined by HRSA to have been sold to covered entities at an above-ceiling 340B price can refuse to remedy that situation with apparent impunity. For example, several manufacturers whose 340B products had been sold to covered entities at above-ceiling prices, according to the OIG's findings in a report issued in 2003, have taken no action to refund the overcharges, despite explicit letters from HRSA directing them to do so, and have suffered no apparent repercussions as a consequence of their refusal to comply with HRSA's directive.

Although, in theory, this situation enables the Secretary of HHS, under the terms of the 340B pharmaceutical pricing agreement, to terminate Medicaid and Medicare coverage of the non-complying manufacturers' products, it is plain that manufacturers do not take this threat seriously, and are content to simply deny that overcharging occurred and refuse to take any remedial action. In the face of this defiance and delay, HRSA has been unable to effectively obtain the refunds that are owed to 340B providers. As manufacturers are well aware, the chances of HHS deciding to deny coverage of a necessary drug for Medicaid recipients because a manufacturer has violated a pricing requirement in the much smaller and less visible 340B program, are virtually non-existent. PHPC believes the only realistic means to remedy this situation would be legislation conferring statutory authority on HHS, through HRSA, to impose meaningful sanctions, such as fines and monetary penalties, on manufacturers that are found to be in violation of their 340B pricing obligations.

As the OIG has suggested, the requisite legislative amendments to the 340B statute could be modeled after the civil penalty authorities in section 1927(b)(3)(C)(i) of the Social Security Act (Act) which governs sanctions applicable to the Medicaid rebate program. In the alternative, we think a minor revision to section 1128A(a)(2) of the Act could expand the authority of HHS, through the OIG, to impose civil monetary penalties in circumstances where a manufacturer has requested payment from a covered entity in violation of an applicable PPA. In fact, we believe simple insertion of the words "or with the Secretary" in the text of section 1128A(a)(2)(B) would accomplish this purpose.

Pricing Transparency

The third major component of an effective strategy for curing current deficiencies in 340B pricing enforcement would be greater transparency in pricing information for the covered entities that actually purchase drugs under the 340B program. Probably the single greatest frustration expressed to PHPC by its members is the fact that they have no basis on which to assess whether they are being overcharged or not for 340B covered products. PHPC receives frequent reports from its members about specific 340B prices that seem inconsistent, excessive, or questionable when viewed in comparison with the prices negotiated by group purchasing organizations (GPOs) or other purchasers in the private market. Yet while these situations give rise to widespread suspicions of overcharging for 340B drugs, there is ordinarily no concrete action that can be taken by a covered entity to seek relief from suspected overcharges because it has inadequate access to relevant pricing information to challenge the manufacturer's alleged 340B price, or even to compile a sufficient factual record to effectively invoke the informal dispute resolution process created by HRSA in federal guidelines.

In light of the resource limitations that have plagued 340B program administration, as well as the historical deficiencies in oversight and enforcement of 340B pricing obligations, it makes undeniable sense to supplement HRSA's compliance-monitoring efforts by empowering covered entities to play a role in verifying that they are paying statutorily appropriate prices for 340B drugs.

Indeed, we believe that more stringent constraints have been placed on covered entities' access to 340B price information than federal law actually requires. Although certain components of the 340B ceiling price calculation utilize confidential data, disclosure of a drug's 340B ceiling price is not tantamount to disclosure of the drug's AMP, best price or any other specific information that the Secretary of HHS is prohibited from disclosing under Section 1927(b)(3)(D) of the Social Security Act. Because calculation of 340B ceiling prices varies depending on how AMP and best price compare and whether an inflationary cap on price increases is triggered, it is impossible to deduce a drug's AMP or best price just from knowing what the ceiling price is.

In addition, the Social Security Act expressly permits the Secretary to disclose any information to the extent such disclosure is determined "necessary to carry out" Section 1927 of the Act, which pertains to Medicaid rebates as well as, in part, to the limitations on prices of drugs purchased by 340B covered entities and the requirement of 340B participation by manufacturers of Medicaid-covered drugs. Accordingly, we believe the relevant confidentiality provisions of the law may permissibly be construed to allow such disclosures of pricing information to 340B covered entities as the Secretary may determine are necessary to effectively administer the 340B program, and that some disclosure of ceiling price information is in fact necessary to such administration. Language in the standard 340B PPA is consistent with this construction of the law, as is legislative history of the 340B statute.

Even if current law is construed to prevent the Secretary's public disclosure of 340B ceiling prices, however, sound administration of the 340B program demands that some

compromise be reached under which covered entities can realistically assess whether they are being or have been overcharged, and bring those situations to the attention of the relevant manufacturers and enforcement agencies. The OIG has recommended that covered entities be afforded secure access to certain pricing data to enable them to detect differences between the prices that they pay and the prices to which they are legally entitled – perhaps through a web-based system by which entities can submit prices and gain a response indicating whether ceiling prices have been exceeded.

PHPC agrees that effective 340B administration demands greater access to price-relevant information by covered entities, and believes that a right to such access should ideally be established by legislative amendment. Nonetheless, we also believe that a more flexible and useful system for affording 340B pricing information to covered entities than currently exists could be implemented by agency regulations or policy issuances, consistent with legal constraints and manufacturers' legitimate security concerns. It is possible, and unquestionably legally permissible, for manufacturers to voluntarily make 340B pricing data available to covered entities, and we strongly urge manufacturers to consider doing so. Absent such voluntary action on a broad scale in the manufacturer community, however, legislative or administrative action must be taken to create some mechanism for reasonable covered entity access to 340B pricing information directly pertinent to the entity's own determination of whether its rights are being violated, such as, for example, authorization for one designated officer of each covered entity (bound by an appropriately structured confidentiality and data use agreement) to have access to 340B ceiling prices strictly for purposes of reporting to HRSA any discrepancy between those prices and the actual purchase prices paid by the entity for drugs. I should note that

GlaxoSmithKline has recently committed to sharing its 340B ceiling price data with the 340B prime vendor program, and that we applaud that action. This is just a first step, however, towards the pricing data accessibility that will be necessary to ensure pricing integrity.

Pharmaceutical Pricing Agreements

There are several other deficiencies in 340B program administration of which PHPC is aware, but which are not within the scope of the OIG's most recent investigation and published report. For example, we understand that there are a number of manufacturers that have avoided or delayed entering into 340B PPAs notwithstanding the continued coverage of their products by Medicaid.

It appears that this situation stems from the fact that there is no defined or regularized process for assuring that manufacturers entering into Medicaid rebate agreements also immediately enter into 340B pharmaceutical pricing agreements as the statute requires. Due to the absence of any such defined process, it seems the obligations of all manufacturers that participate in Medicaid to enter into 340B PPAs have not been uniformly enforced. Some manufacturers have restricted the scope of their 340B obligations by having subsidiaries enter into the PPAs on behalf of only certain manufacturer "business units" (instead of the entire corporate entity manufacturing Medicaid-covered pharmaceutical products), or by executing PPAs through mid-level corporate representatives whose authorities to bind the corporations extend only to isolated business units. We have also heard, in some instances, of manufacturers of

Medicaid-covered drugs taking months or years before they sign any 340B agreement at all.

To address these problems, a routine administrative process must be instituted that, at a minimum, assures that a corresponding 340B program PPA is executed contemporaneously with any Medicaid rebate agreement executed between a manufacturer and the Secretary, or within a short, specifically defined time period thereafter. HHS should also clearly designate the agency personnel responsible for obtaining timely and properly executed PPAs and provide for adequate HRSA review of PPAs to verify that they apply to a scope of pharmaceutical products corresponding to the scope of Medicaid coverage of the relevant manufacturer's entire product line.

In addition, although PHPC is cognizant of questions that have been raised as to the present enforceability of the standard pharmaceutical pricing agreement between the Secretary and manufacturers, we believe that certain revisions of that document would facilitate more effective program administration and compliance enforcement. At present, the PPA represents the only direct source of legal obligation on the part of a manufacturer to comply with 340B pricing limitations or other requirements. Yet the manufacturer responsibilities expressly referenced in that agreement are quite limited, and extend little beyond agreeing to charge 340B entities at or below the applicable ceiling prices.

We believe a number of amendments to the PPA could and should be made to address systemic problems of administration and weaknesses in program enforcement that have

been noted in the recent OIG report and discussed in my testimony before the Subcommittee. In particular, PHPC believes that the standard 340B PPA should be revised in some or all of the following ways:

- The PPA should require manufacturers to submit the 340B ceiling prices calculated for their drugs to HRSA for purposes of comparison with HRSA's calculations based on CMS data.
- It should require manufacturers to disclose the 340B ceiling prices they calculate for their drugs to designated officers of covered entities, under appropriate confidentiality and data use agreements and security mechanisms, to be established by the Secretary through regulations or policy issuances.
- It should expressly require manufacturers to make all of their covered drug products available to covered entities for purchase at 340B prices.
- It should require manufacturers to calculate and refund 340B overpayments to covered entities, under a procedure to be outlined by the Secretary in published regulations or policy guidance, whenever it is finally determined by the manufacturer or HRSA that 340B overcharges have occurred.
- It should obligate manufacturers to participate in and abide by decisions rendered pursuant to an administrative process established for resolution of pricing disputes.
- It should require a manufacturer to calculate and apply 340B pricing retroactively to any purchases of covered drugs made by covered entities during any significant lag-time that may elapse between execution of the manufacturer's Medicaid rebate agreement and its 340B PPA, and to make appropriate retroactive refunds consistent with such calculations.
- It should require manufacturers to pay covered entities interest on refunds for past overcharges.

In other words, until legislation is passed or regulations are promulgated to implement the OIG's recommendations, amendment and expansion of the standard 340B PPAs may offer an alternative means to some immediate amelioration of programmatic deficiencies.

Refund Procedures

We also believe that a specific policy needs to be developed by HRSA requiring manufacturers to issue refunds to covered entities whenever it is discovered or finally determined that they sold 340B drugs at above-ceiling prices, and that such a policy should provide detailed procedures on how to calculate and issue the refunds. There are a number of different scenarios under which the existence of a 340B overcharge may be established. In some instances, particularly if HRSA oversight of the 340B program is enhanced pursuant to recommendations discussed at this hearing, HRSA may determine that an overcharge has occurred or – as was the case with certain drug sales scrutinized in the OIG’s March 2003 report and investigation – the OIG may find that covered entities have been overcharged. In other instances, a manufacturer itself may become aware that it has miscalculated AMP or best price for a drug, and that consequently both Medicaid rebates and 340B ceiling prices have been inaccurately computed. In the latter scenario, there is a defined set of procedures established by CMS to facilitate retroactive adjustments of rebate payments to the Medicaid program, but no parallel process for repayment of 340B overcharges.

Thus we believe that HRSA needs to develop and define a refund process to be implemented contemporaneously with CMS rebate adjustment procedures, where manufacturers retroactively correct AMP or best price calculations. Furthermore, in any and all other circumstances in which manufacturer overcharges for 340B drugs are found to have occurred, there should be a clearly defined process, established by HRSA, that

manufacturers are obligated to follow to afford appropriate refunds of 340B overcharges to affected covered entities.

Drugs in Short Supply

Another frequent topic of complaints that PHPC has heard from its members concerns drugs that are reportedly in short supply and are therefore not being made available to covered entities at 340B prices. According to our members, there have been a number of instances in which covered entities were told by manufacturers that particular products – especially intravenous immune globulin (IVIG) and other blood-derived products – are unavailable for purchase under the 340B program because all available supplies of the products have already been committed to other purchasers under commercial contracts. Often in these situations, the products at issue were readily available for purchase on the commercial market or through group purchasing organizations at prices above 340B ceiling prices, even though they were ostensibly in such short supply that they could not be sold under the 340B program.

This problem is especially serious for disproportionate share hospitals in the 340B program since they are prohibited under the 340B statute from purchasing covered outpatient drugs through their GPOs. Unable to buy product at a 340B price because of a shortage problem, the hospitals are faced with the impossible dilemma of having to either violate federal law by purchasing the drugs at GPO prices, buy the drugs at higher, retail prices that the institution cannot well afford, or deny their patients access to the drugs altogether.

Although HRSA has issued a letter stating its position that manufacturers may not discriminate against 340B entities in allocating drugs that are in short supply, PHPC believes that additional protections are needed to adequately address this problem. HRSA should audit or otherwise review the allocation methods used by manufacturers to ensure that they are not discriminatory and that they do not have a discriminatory effect. Moreover, because large purchasers such as GPOs and managed care organizations have an advantage over smaller purchasers by virtue of being able to contract for most or all of the remaining drugs available, the 340B prime vendor should be directed to take an active role in purchasing drugs in short supply at the request of covered entities. Perhaps most importantly, we believe HRSA should issue a specific policy that not only addresses covered entities' access to 340B pricing for covered outpatient drugs in short supply, but also reinforces the point that Congress' clearly expressed intent in the 340B statute is for covered entities to be able to actually purchase covered drugs at 340B prices, not just to enjoy theoretical discounts on products that are not made available under the program at all.

Effective Dispute Resolution

PHPC also believes that an important step towards enhancing the accountability of manufacturers for pricing violations and empowering covered entities to assist HRSA in monitoring and enforcing pricing compliance, would be institution of an administrative process to resolve disputes between covered entities and manufacturers relating to 340B prices and purchases that culminates in a final and judicially reviewable agency decision.

The capacity of covered entities to effectively pursue relief from above-ceiling charges by manufacturers for their drugs is presently unclear. The dispute resolution process defined by HRSA guidelines is not binding on manufacturers. Certain putative class action lawsuits now pending in federal and state courts may test whether common law, third-party beneficiary rights under a contract, or anti-fraud provisions permit covered entities to initiate and pursue court actions for recovery of past overcharges, but disposition of those cases and questions is unlikely in the near future.

PHPC has previously advocated legislative amendments clearly conferring on covered entities a specific, statutory, private right of action against manufacturers for recovery of 340B overcharges, but believes covered entities' rights and interests in being able to independently pursue relief from 340B overcharges might also be protected by the development of suitable administrative procedures. Specifically, the administrative process we envision would be one through which covered entity and manufacturer contentions and evidence of a 340B price dispute would be reviewed and adjudicated by a federal agency decisionmaker, who issues a final agency decision respecting the controversy. Formal, duly promulgated regulations would be the preferable means of defining and establishing such procedures, so that the agency's decision pursuant to the process would have legally binding effect on the parties in the absence of further review by a court. PHPC believes and hopes that the availability of such an administrative process, as well as implementation of the other programmatic reforms I have described, would greatly reduce the likelihood of covered entities deciding that they need to initiate litigation in the courts to enforce their rights to proper 340B pricing.

Conclusion

In conclusion, PHPC would like to commend the OIG for its fine work in assessing some of the problems and complexities of the 340B program as currently administered, and formulating recommendations for change and improvement. My testimony here today by no means comprehensively addresses all of the areas in which there is a need for federal attention and action. However, in the view of PHPC, each of the measures I have suggested is vital to the improvement of the 340B program and to the successful attainment of its statutory goals in both the short and long-term. PHPC would like to thank the Subcommittee for holding this important hearing. I appreciate the opportunity to testify before you today on these critical matters and look forward to addressing any questions that Subcommittee members may have for me.

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William von Oehsen, a principal in the law firm Powers, Pyles, Sutter and Verville P.C. (PPSV), has extensive experience in general health law, legislation and policy, especially in the areas of pharmaceutical pricing, materials management, and third party reimbursement, and food and drug law.

With respect to Mr. von Oehsen's pharmaceutical pricing practice, PPSV offers a wide range of services involving federal and state regulation of drug prices and reimbursement. The U.S. pharmaceutical market is unique in that pricing is regulated, either directly or indirectly, under a complex array of federal and state laws designed to make prescription drugs more affordable to government programs and providers, as well as to seniors and other vulnerable populations. As prescription drug prices continue to climb at double digit inflation rates, the demand for expertise in these laws has also grown. It is not surprising, therefore, that drug pricing has become one of Mr. von Oehsen's most active practice areas.

Mr. von Oehsen serves as general counsel to the Public Hospital Pharmacy Coalition (PHPC) which was launched more than ten years ago to help high-Medicaid public and non-profit hospitals take advantage of a federal law – section 340B of the Public Health Service Act – that requires pharmaceutical manufacturers to give drug discounts on covered outpatient drugs as a condition of the Medicaid program covering and paying for those drugs. As membership for PHPC has grown, expertise on 340B matters and related drug pricing laws has deepened such that Mr. von Oehsen has become a national leader in this area. He was instrumental in forming the 340B Coalition, a coalition of approximately sixteen national organizations whose members collectively comprise all the entities that are eligible to participate in the 340B program. The 340B Coalition hosts an annual conference for safety net providers, industry, wholesalers and policymakers, that, as a result of its popularity and broad attendance, now serves a major forum in which national drug pricing policy issues are addressed. PPSV is responsible for organizing this annual event and delivering regular presentations on recent developments – regulatory, legislative and judicial.

The 340B program is one of four federal drug discount programs and, because one cannot truly understand federal regulation of drug pricing without an understanding of how these programs interrelate, Mr. von Oehsen has expertise in each of these federal areas. They include the Medicaid drug rebate program, the federal supply schedule and the federal ceiling price. States have also been active in helping individuals, especially seniors and low-income patients, access affordable drugs, and many of these efforts build upon the federal programs. Accordingly, Mr. von Oehsen's drug pricing client base includes a growing number of states that are seeking to lower drug costs for state-funded populations, such as Medicaid recipients, Medicaid expansion populations, prisoners,

mental health and other long term care patients, and state employees. Mr. von Oehsen regularly testifies before state legislatures and executive branch officials. Another area of collaboration with states relates to numerous ongoing investigations into potential violations by industry of federal and state drug discount laws and efforts to recover overpayments from industry.

As a result of Mr. von Oehsen's expertise in the drug pricing and FDA areas, he has found himself serving a growing number of pharmacies, both freestanding and institutional, in various legal and regulatory matters. His pharmacy-related projects have involved analysis of federal laws such as Robinson-Patman and the Non-Profit Institutions Act, DEA registration, the Prescription Drug Market Act, Medicare/Medicaid coverage and reimbursement of pharmaceutical care and federal fraud and abuse laws such as Stark and anti-kickback. At the state level, he has state licensure laws. PPSV also assists pharmacy clients with their transactional and litigation needs.

In the food and drug area, Mr. von Oehsen guides companies through the FDA's premarket clearance process; assists companies with product development strategies; provides labeling, advertising, manufacturing and import/export advice; and handles other issues that arise during the progression from initial clinical testing through commercial distribution. He also works on the development and distribution of medical devices, biologics, food, food additives, dietary supplements, animal feeds, and cosmetics. He has also defended clients against FDA enforcement actions. Mr. von Oehsen has lectured and published articles on food and drug related issues.

In addition to his drug pricing and FDA practices, Mr. von Oehsen has considerable experience in advising clients on materials management, managed care, and general health law issues. He works with Medicare/Medicaid and other third-party payment programs, hospitals, HMOs, PPOs, physician groups, and other health care providers. He counsels clients on such issues as managed care, fraud and abuse, third-party reimbursement, mergers and acquisitions, state licensure of health professionals and providers, and confidentiality of records. He also has significant advocacy experience on health legislative issues, including in the areas of drug pricing, managed care, AIDS, long-term care, and Medicare/Medicaid. Mr. von Oehsen is co-author of a book concerning Medicare/Medicaid managed care and state health reform.

Mr. von Oehsen is a member of the District of Columbia Bar. He received his law degree from Georgetown University Law Center in 1988 and a masters from Harvard University in 1984. He earned his undergraduate degree from Princeton University in 1981. Mr. von Oehsen participates in a number of professional organizations including the Food and Drug Law Institute (where he was an Annual Scholar), the American Health Lawyers Association and the American Association of Health Plans. He was also a founding director of the Family AIDS Housing Foundation, now called Building Futures: Family AIDS Housing.

Concentrating in Health Legislation and Policy, Pharmaceutical Pricing, and Food and Drug law, Principal, Powers, Pyles, Sutter & Verville, P.C., Washington, D.C.

EDUCATION

- J.D., Georgetown University Law Center, 1988
- M.T.S., Harvard University, 1984
- A.B., Princeton University, 1981

BAR ADMITTANCE

- Admitted to the District of Columbia Bar, 1990
- Admitted to the Pennsylvania Bar, 1988

MEMBERSHIPS

- Food and Drug Law Institute
- American Health Lawyers Association
- American Association of Health Plans
- Founding Director, Family AIDS Housing Foundation, Inc.
- Annual Scholar, Food and Drug Law Institute, 1978-88