



## Public Hospital Pharmacy Coalition

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(A Coalition of the National Association of Public Hospitals and Health Systems)

### Comments of the Public Hospital Pharmacy Coalition on "Patient and Physician Concerns in Access to Intravenous Immunoglobulin"

Hosted by the Department of Health and Human Services (HHS),  
Office of the Assistant Secretary for Planning and Evaluation (ASPE).

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I am Edith Marshall, and I am speaking today on behalf of the Public Hospital Pharmacy Coalition, known as "PHPC" – an association of close to 400 disproportionate share (or "DSH") hospitals that participate in the so-called "340B Drug Discount Program" established under the Public Health Service Act and the Medicaid statute. Under the 340B program, companies that manufacture drugs covered by Medicaid or by Medicare Part B are obligated to afford significant discounts on the purchase of covered drugs to qualifying safety-net providers such as DSH hospitals serving a particularly high percentage of indigent patients, community health centers, Ryan White clinics, and other qualifying facilities identified by in the governing statutes. The discounted 340B prices for drugs are similar the discounts manufacturers are required to afford the Veterans' Administration and the Medicaid program through payment of statutory rebates, and are subject to a statutorily defined ceiling. Charging a 340B covered entity a price for a drug that is above the 340B ceiling price violates formal, written Agreements manufacturers must execute with the Secretary of the Department of Health and Human Services, as well as the legislative mandate of section 340B of the Public Health Service Act.



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340B hospitals and their patients, like many other healthcare providers and the individuals they serve, have been experiencing severe difficulties in obtaining adequate supplies of IVIG products. Indeed, based on a survey of its members conducted by PHPC earlier this year, only about half of PHPC's member hospitals are able to obtain enough IVIG to fulfill the treatment needs of their patients. We are not in a position to definitively determine the most significant cause of the problem, nor can we state with certainty whether there is an actual shortage of IVIG product on the market as a whole. But both the information provided by the sample of 340B hospitals responding to PHPC's recent survey, and the less formal reports and anecdotal accounts of difficulties obtaining IVIG that we have persistently received from our membership over the past year, confirm that the problem of gaining access to IVIG faced by safety net hospitals and the disproportionately indigent patient populations they serve is one of crisis proportions.

The 340B covered hospitals we represent, however, also face special problems with regard to IVIG access that are distinct from the generalized problems of product access and availability that, as we are hearing today, are so widespread in the healthcare and patient community. Specifically, because our members serve large numbers of indigent and often uninsured patients who cannot pay for their healthcare, or who can only pay for a small percentage of its costs, these hospitals rely heavily on the discounts they are entitled to receive under the 340B program to enable them to stretch their limited resources to provide pharmaceutical and other care to a vulnerable population. With respect to IVIG, these hospitals are facing not only a supply crisis, but a budgetary crisis as well.

Despite the clear legal obligation of drug manufacturers to offer IVIG for purchase by 340B covered entities at or below the discounted, 340B price, manufacturers are only

infrequently offering IVIG product for purchase at 340B prices. Almost 80% of the hospitals in our survey sample, in fact, reported being unable to obtain **any** amount of IVIG at the 340B prices to which they are supposed to be entitled under the law, even though close to 70% of the sample reported being able to obtain IVIG at higher prices through regular wholesale and distribution channels, and roughly 50% of responding hospitals have been able to obtain enough IVIG product to fulfill their patients' needs. The result is that 340B hospitals – which are under restrictions from even using Group Purchasing Organizations to buy outpatient drugs, by virtue of their participation in the 340B program – are forced to pay prices for IVIG far in excess of what they can afford, and of what applicable laws intend them to pay.

We have been told that manufacturer representatives “in the field” characteristically cite a “shortage” of IVIG product as the reason that 340B pricing is unavailable, but the data gathered in our recent member survey, and which I have already mentioned today seems to belie that explanation. It is not that IVIG is unavailable at the 340B price because it is simply unavailable for purchase by 340B providers – to the contrary, as the survey data I have cited confirms, significant amounts of IVIG are available for purchase by 340B providers as long as they are willing and able to pay high enough prices. Although it is still very hard to discern, let alone to document, precisely what is occurring here with respect to manufacturers' fulfillment of their 340B program obligations, it appears that the situation bears some similarity to an elaborate shell-game. We have been assured by manufacturers that they do indeed offer IVIG at 340B prices, as the law requires. However, for the most part IVIG manufacturers have also announced that, unlike most outpatient drugs, IVIG can be purchased at a 340B price only directly from the manufacturer, and not through a 340B provider's regular wholesaler. When a 340B hospital tries to actually purchase IVIG from the manufacturer under a 340B contract, however, the provider is

usually told that unfortunately there is no longer any of the product available for purchase under that contract, because all of the available IVIG supply has already been committed to other purchasers – such as specialty distributors – under commercial contracts that the manufacturer is obligated to comply with, and that the 340B entity is therefore best advised to go to one of these distributors and purchase IVIG on the open market.

Specialty distributors and wholesalers with IVIG product for sale, when asked to offer it for purchase at a 340B price, protest that it is drug manufacturers, not distributors, that are required to offer discount prices to 340B entities, and that the drug manufacturers have made it clear that no “charge-back” (that is, the mechanism through which manufacturers standardly reimburse wholesalers for 340B discounts provided on covered outpatient drugs) will be permitted or implemented on IVIG products. Nobody – not manufacturers or distributors of IVIG – seems to be willing to put in writing an explanation of what is going on and why it is becoming impossible to purchase IVIG under the 340B program. In short, while the manufacturers of IVIG pay appropriate lip-service to their obligations to 340B entities to sell their product at discounted prices, the market has been structured so that this seldom actually occurs. A shortage of IVIG on the market – whether one actually exists or not – does not adequately explain what we are seeing in the realm of IVIG pricing, and we cannot help from suspecting and speculating that perhaps some element of profit-motive and reluctance to provide discounts on a high-priced product is at work, in addition to whatever overall supply problems may – or may not – exist.

In summary, at least from the special perspective of the 340B hospital community, there appears to be more going on here than a simple mismatch of supply and demand. There seems to be no rationale explanation for the fact that manufacturers – certainly aware that, as has been

widely publicized and the media and recognized by responsible federal agencies, demand for IVIG has shifted to a substantial degree away from physicians' offices and to hospitals – still insist on holding providers to strict “allocations” of IVIG based on historical use and purchase levels pre-dating the increased demand for IVIG in hospital settings. There seems to be no rational explanation for why – if a product “shortage” is the ostensible reason 340B providers cannot get the discounts on IVIG – hospitals are able to buy IVIG at inflated prices so much more frequently than they can purchase those same products at the lower prices they are entitled to. We applaud the federal government's efforts to look further into this entire situation, and are hopeful – for the sake not only of 340B providers and their patients but all the providers and patients that desperately need adequate supplies of these life-preserving drugs -- these efforts will yield significant changes in the way IVIG is allocated, distributed, and priced on today's market.