

# THE 340B COALITION

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November 19, 2010

CDR Krista Pedley  
Director, Office of Pharmacy Affairs  
Health Systems Bureau  
Health Resources and Services Administration  
5600 Fishers Lane  
Parklawn Building, Room 10C-03  
Rockville, MD 20857

## **Re: Comments on 340B Drug Pricing Program Administrative Dispute Resolution Process**

Dear CDR Pedley:

On behalf of the thousands of providers enrolled in the 340B federal drug discount program, the 340B Coalition respectfully submits this letter in response to the Advance Notice of Proposed Rulemaking (ANPRM) and Request for Comments issued on September 20, 2010 regarding the 340B drug pricing program administrative dispute resolution process. With this comment, the Coalition seeks to ensure that the dispute resolution process is fair, adequate, efficient, and effective for all parties involved.

The 340B Coalition consists of eleven national organizations representing the thousands of safety net providers and programs that participate in the 340B program. The Coalition was created to assist providers with accessing and complying with the program while working with the federal government to improve program implementation and integrity.

### **(1) Administrative Procedures Generally:**

An overarching challenge that exists in establishing a meaningful and useful administrative dispute resolution process for the 340B program stems from an inherent imbalance in resources available for litigation or dispute resolution between most safety net health care providers that qualify as 340B covered entities and even an average-sized pharmaceutical manufacturer. By definition, 340B providers are generally entities whose financial resources are scarce and stretched; they are unlikely to have either staff or financial resources to support any protracted, complex, or burdensome process of dispute resolution, whether on an administrative level or in litigation before a court. A fair and meaningful 340B dispute resolution process must therefore be simple and stream-lined, as well as effective. The Coalition's comments and suggestions have been formulated with a view towards achieving this goal.

### **(2) Existing Models:**

The unique character of the 340B program militates against wholesale adoption of any one, existing administrative dispute resolution model that has been developed for a different program or purpose. However, the Coalition suggests that the procedures for debarment and suspension from government procurement processes (see 2 CFR Part 180) offers many useful elements that

would be appropriate to incorporate into a 340B dispute resolution system. Specifically, we suggest that the 340B process should include the following features: (1) the decision maker(s) should be impartial and insulated to the extent possible from inappropriate influence and retaliation based on its decision; (2) the standard for decision by that official is a "preponderance of evidence" standard, defined as "proof by information that, compared with information opposing it, leads to the conclusion that the fact at issue is more probably true than not"; (3) proceedings may be relatively informal, but provide due process in the sense of each party's right to be heard; (4) decisions are ordinarily made on a paper record, but if the deciding official decides there are genuine issues of material fact in dispute (or if a party requests), he/she may conduct a fact-finding hearing at which witnesses may be heard and the proceedings at which will be transcribed unless waived; (5) the deciding official must issue a written decision explaining reasons for the decision; (6) the deciding official may take mitigating or aggravating factors into account; and (7) a party may seek and obtain reconsideration in exception circumstances, i.e., new evidence that comes to light post-decision.

Although we recommend that the above features be included in the new 340B dispute resolution process, we also believe that a suitable process needs to be built "from the ground up" based on the uniqueness of the program and the problems it presents. These problems include, for example, the pervasive imbalance of resources mentioned above, and the historical obstacles to covered entities being able to discern the single most crucial fact involved in a 340B overcharge case – the applicable 340B price. So expanding the reach of existing tribunals within the Department of Health and Human Services (DHHS) to adjudicate 340B-related disputes simply will not work. The Coalition further recommends against attempting to utilize the current, voluntary dispute resolution process described in 340B program guidelines as a model in any significant respect. We believe that the infrequency of use of that process by 340B program stakeholders was attributable to more than its voluntary nature, and was related to a combination of uncertainties and complexities that permeated the process.

### **(3) Threshold Requirements:**

The Coalition agrees that there should be a threshold standard for initiating the dispute resolution process. The initiating party should be required to show that it has more than mere allegations of another party's violation of program rules and requirements. We believe the appropriate standard to initiate an allegation is whether there is "adequate evidence," also drawn from the debarment regulations mentioned above, which can be likened to "probable cause." We do not think that the standard for agency inquiry should require a party to be prepared to provide a full statement of all relevant facts, issues, and reasons for the party's position at the very inception of the dispute resolution (as was required under the voluntary dispute resolution guidelines). A manufacturer might possibly be able to meet this standard because it has a right to audit a covered entity for compliance with program rules (as is a statutory prerequisite to a manufacturer's initiation of a dispute to which the new administrative process will apply). It is very unlikely, however, that a covered entity – especially a small, understaffed, and sparsely funded safety net health care facility – will have the capacity to obtain the required documentation from the manufacturer, to marshal comprehensive support for its allegations, and set out its case in this degree of detail at the beginning of the dispute resolution process, before there has been an opportunity for discovery.

We believe that a significant problem with the existing voluntary procedure is that it requires the aggrieved party to demonstrate that there is a “genuine and substantial issue of material fact in dispute.” This enables the accused party to simply not respond to the facts alleged so that there is no “dispute.” Rather, if the party is able to demonstrate “adequate evidence” of a violation, but the opposing party fails to respond to the allegation, then the decision maker may issue a decision solely upon the evidence presented. This will certainly motivate the accused party to provide evidence supporting its position. It will also ensure that all allegations will be appropriately addressed and resolved. In fact, we recommend that the procedures set forth the specific types of documents that must be provided by the parties.

Furthermore, we recommend that in all cases where the 340B price is disputed, the manufacturer should be asked by the agency decision maker to produce documents to support its determination of the drug’s average manufacturer price (AMP) and best price (BP). Such documents would include the identification of the appropriate classes of trade used in the AMP and BP calculations, the manufacturer’s daily sales reports by class of trade, disclosure of all discounts associated with those sales to ascertain the net price, and any contracts with wholesalers and distributors which may impact the price charged. Likewise, the covered entity can be directed by the agency decision maker to provide documentation, such as invoices, contracts, and billing records, to establish proper charges for 340B pharmaceuticals. The agency can maintain the confidentiality of this information.

Even further, we recommend that the agency decision maker should instruct the opposing party to submit certain required documentation upon which he/she may determine whether there is a “material factual dispute” and therefore decide whether a hearing is necessary with additional testimony or document production, or whether a decision can simply be made based upon preponderance of the evidence submitted. We prefer the process used in the debarment regulations where the decision maker can rely upon the documentation submitted and/or can make his or her own determination, whether requested by a party or not, that there is a material factual dispute and a fact-finding hearing is necessary.

The Coalition, therefore, believes that the standard for initiating a dispute resolution proceeding should be one of adequate evidence, defined (as in federal debarment/suspension process, as referenced above) as information sufficient to support the reasonable belief that a particular act or omission has occurred. The individual or entity that decides whether this threshold has been reached should not be the same individual, tribunal, or entity that will conduct the fact-finding hearing or ultimately make a decision on the dispute.

In the Coalition’s view, there is no question that where a manufacturer’s refusal to sell a covered outpatient drug at a 340B price has required a covered entity or entities to purchase the drug at full price, this circumstance should be regarded as overcharging for a 340B drug in violation of the statutory mandate. In this scenario, even if the 340B entity does not deal directly with the manufacturer to purchase the drug, the manufacturer has effectively, even if indirectly, charged the 340B entity full price for its drug.

We agree that some effort to explore settlement of a dispute should take place before a DHHS representative is called upon to resolve a dispute through a determination that will stand as an agency decision. However, we do not think that requirement of a “good faith effort to settle the dispute” is particularly meaningful as a prerequisite to initiation of a dispute process. Based on covered entity experience over the years since the current alternative dispute resolution guidelines have been in effect, our impression is that too frequently inquiries or complaints to manufacturers concerning perceived overcharging for 340B drugs are simply ignored; and the only “effort to settle” a dispute that is possible for a covered entity is a unilateral communication to the “offending” manufacturer. In light of this reality, we recommend that no fewer than 30 days prior to initiation of a dispute resolution proceeding, the initiating party should simply be required to give the potential opposing party written notice of the subject matter of the dispute (*i.e.*, the alleged noncompliance at issue), and information as to how, when, and to whom contact may be made in order to informally attempt to resolve the dispute without initiation of dispute resolution.

In addition, we think consideration should be given to requiring a mediation step in the dispute resolution process, prior to submission of a matter to a decision maker. In other words, the parties could be required, within a defined period after initiation of an administrative dispute resolution matter and before any information is submitted to the decision-making official, to meet with each other’s representatives in the presence of an unbiased third-party who will attempt to facilitate or mediate settlement discussions between the parties. Mediation meetings need not be, and should not be required to be, in-person and face-to-face, unless both parties desire to proceed in that fashion and it is convenient to both parties. A video conference, telephone call, or any other method of meeting that is mutually acceptable to the parties should be permissible for this purpose, with the caveat that the mediator must communicate with each involved party by the same means. Acceptable mediators might be, for example, volunteers from the DHHS’s Office of General Counsel who are familiar with mediation processes from the perspective of federal litigation, administrative proceedings, or alternative dispute resolution involving DHHS, or other individuals who volunteer time, through a local bar association or otherwise, as mediators in litigation matters. This feature would assure that disputes are informally resolved wherever possible, and in our view would be more effective in achieving that goal than an unsupervised, pre-initiation settlement-effort requirement that invites a pro-forma approach.

#### **(4) Hearings:**

As mentioned above, the 340B Coalition supports a relatively informal hearing process before an agency decision maker, allowing each party a fair opportunity to be heard through the submission of a paper record and, if the party chooses, a memorandum explaining why the documentary evidence before the decision maker supports the party’s contentions. As we discuss in further detail below in reference to the matter of discovery, we also recommend that the information available to the decision maker should include certain standard types of evidence that will be generated or obtained, and provided to the decision-making official, by responsible components of the agency rather than directly by the parties to the dispute. We believe it is important that *ex parte* contacts between any party and the decision-making official be strictly prohibited. We suggest that requirements as to the form of submissions by the parties should not

be stringent, but that each party must transmit copies to any opposing party of any and every document submitted to the decision-making official, contemporaneous with such submission to that official. The process should provide for the consideration of motions and additional submissions such as post-hearing briefs only in exceptional circumstances, such as where the decision-making official conducts an evidentiary hearing and requests post-hearing briefs to clarify matters that he/she found particularly confusing or unclear. We think it is important, however, for the dispute resolution process to be one that can realistically be utilized by a covered entity without the expense of representation by legal counsel or having to adhere to the rules of civil procedure. Accordingly, we believe it would be unwise to build too many formal “briefing” requirements, or procedural complexities in the nature of multiple layers of formal administrative review (such as rehearings), into the system. A decision-making official should, however, always have the discretion to grant a rehearing to a party or afford a reconsideration in exceptional circumstances, such as where new evidence has been discovered, or there is post-hearing evidence of deception or fraud.

As already discussed, the Coalition recommends an evidentiary/decision-making standard of preponderance of the evidence. We do not recommend that parties to administrative 340B disputes be able to obtain issuance of subpoenas for documents or witnesses. However, as is explained elsewhere in these comments, we believe it would be appropriate for the subpoena power of DHHS’s Office of the Inspector General (OIG) to be used in support of 340B dispute resolution. In keeping with the goal of creating a reasonably simple and “user-friendly” process, we do not recommend that there be an array of potential sanctions that parties may seek to have imposed on their administrative “opponents.” We do recommend that the decision-making official should have authority to sanction any party for willful and intentional deception in the course of, or failure to cooperate with, the dispute resolution process, by finding that the party has thereby forfeited its case.

**(5) Decision-Making Official or Body:**

As already stated, the 340B Coalition favors a decision maker, whether it be a single individual or a committee, panel, or other tribunal, provided that such decision maker is impartial and insulated to the extent possible from inappropriate influence and retaliation based on its decisions. The decision maker should not include political appointees but rather civil servants of a higher grade who have these protections and may be well-suited for this process. We do not think that the decision maker should be the same individual or group of individuals charged with deciding the sufficiency of a party’s contentions to initiate a dispute resolution. We recommend that an official within DHHS be appointed to serve this latter function – possibly an attorney or investigator within the OIG. We would have no objection to appointment of a decision-making official from within the Health Resources and Services Administration (HRSA), although we do not believe that an individual qualified to serve this function must necessarily have prior experience specifically with HRSA programs. We would strongly oppose, however, designating an official or staff member from the Office of Pharmacy Affairs (OPA) as the dispute resolution decision official. The critical attribute of such an official must be complete objectivity and lack of bias towards or against any involved party to the dispute. The necessarily close working relationship between OPA and 340B stakeholders in regard to a variety of issues makes it

difficult to guarantee that any member of that office would not be, or be perceived to be, biased in one direction or another.

We believe that the role of OPA in administrative dispute resolution should be limited to functions such as (1) monitoring the effectiveness of, and coordinating the efforts of other components of DHHS in relation to, the process; (2) serving as a resource for basic information to parties or potential parties as to the applicable rules and procedures; (3) conducting basic training with respect to the 340B program for individuals unfamiliar with the program who have volunteered or been appointed to serve as mediators, final decision makers, or arbiters of the sufficiency of threshold allegations to initiate dispute resolution.

**(6) Appropriate Appeals Procedures:**

Again, the Coalition is concerned that the addition of layers of administrative appeal, beyond the determination of a single decision-making official, will result in a process that is too protracted and resource-intensive to be of any significant utility to covered entities whose personnel and financial resources are already stretched to the breaking point. Although we comprehend the potential benefits of interposing an administrative appeals process between determination by an initial decision official and adoption of a determination as a final agency decision subject to review under the Administrative Procedure Act (APA), on balance we believe that such a process with any degree of formality would discourage 340B providers from seeking dispute resolution at all. We recommend that, in lieu of a formal administrative appeal, any party to a 340B dispute resolution should be able to request review by the Administrator of HRSA of a determination made by the 340B dispute decision official; and upon such request the Administrator (or his/her designee) must conduct a review (similar to the review of Provider Reimbursement Review Board decisions made by the Administrator of the Centers for Medicare and Medicaid prior to deciding whether to reverse or adopt those decisions), and determine whether the underlying decision will or will not be adopted as the agency's decision. This process should be triggered by a simple request for review; and should neither require nor permit further submission of memoranda or briefing by the parties to the dispute.

**(7) Deadlines:**

The Coalition suggests that any time-bar applicable to covered entities that may wish to initiate dispute resolution proceedings should date from the point in time that a covered entity gains actual knowledge of overcharging by a manufacturer. An appropriate time frame might be within 180 days of gaining such knowledge. In the case of a manufacturer alleging violations by a covered entity, however, the appropriate deadlines may be somewhat different due to the statutory requirement of an audit preliminary to initiating dispute resolution. We propose that a manufacturer's initiation of dispute resolution should be time barred if it does not seek such initiation within no more than 90 days of completing its audit, and within no more than 180 days of its gaining the information based on which it determines to proceed with conduct of the audit. Deadlines for response to submissions by the parties should be established by the decision official based on the complexity and magnitude of specific submissions, but in general should not be less than 30 days. Consequences for failure to meet a deadline should be determined flexibly by the deciding official, based upon the involved party's explanation of the reason for

such failure, but should include, as appropriate in extreme cases, waiver of the right to have a submission considered by the decision maker or forfeit of the case.

**(8) Discovery Procedures:**

The Coalition views discovery as a prime aspect of dispute resolution that could skew the fairness of the process due to an imbalance of resources between parties to the dispute. In order to avoid this danger, as well as to conserve the resources of all parties and promote full and fair consideration of all the facts relevant to a dispute, we strongly advocate the inclusion of “automatic” discovery by the parties of certain standard categories of factual information, assisted by OPA and other components of DHHS. As previously mentioned, in a covered entity-initiated dispute concerning an allegation of overcharging for 340B drugs by a manufacturer, the decision-making official and the parties should, as a matter of course, be furnished with OPA’s calculation of the 340B ceiling prices for the drugs as well as the manufacturer’s calculation of the 340B ceiling prices and pertinent data supporting the values assigned by the manufacturer in that calculation to any other pricing metrics (*e.g.*, AMP and BP) that are used in determining the 340B prices. See our comments above in (3) for other documents that should be produced automatically in an overcharge dispute. Note that HRSA is required under the Affordable Care Act to calculate the 340B ceiling price based on data available to DHHS under the Medicaid statute.

To the extent that the records of a wholesaler, or other third party, are pertinent to a dispute, the OIG should be charged with acquiring those records (by subpoena or otherwise) and furnishing them to the decision official and the parties. We note the subpoena powers of the OIG under the OIG Act of 1978, as amended, are sufficient to extend to issuing subpoena’s in support of the dispute resolution process. (See 5 USC App 5 Sec. 6 (a)(4)). We also note that under subsection (d)(1)(B)(v) of the 340B statute, as amended by the Affordable Care Act, improvements to 340B program integrity are required to include selective auditing of manufacturers *and wholesalers* to ensure the integrity of the 340B drug discount program. We believe this statutory charge also supports the conclusion that the DHHS, through its OIG or otherwise, has authority to obtain wholesaler records and information that is pertinent to enforcement of 340B program rules and standards, and to use those records for purposes of assuring 340B compliance, including through support of the administrative dispute resolution process.

Discovery procedures above and beyond this automatic discovery should be closely monitored and limited by the agency decision maker to assure that neither party engages in overly extensive or burdensome discovery processes, engages in discovery substantially disproportionate to the discovery conducted by the other party, or uses discovery to wage a “war of attrition” against an administrative opponent.

We agree that the confidentiality of certain information obtained in an automatic discovery process, as well as through other discovery mechanisms, will need to be protected, and suggest that parties to a dispute resolution proceeding be required to enter into appropriate confidentiality agreements for the protection of that information, as a condition of initiating a dispute proceeding or of being deemed to meet the standard of cooperation in the proceeding necessary

to avoid forfeiture of the case. However, the outcome of the dispute should not be confidential, even if the parties settle their differences themselves.

**(9) Manufacturer Audits:**

The Coalition regards the current manufacturer audit guidelines as adequate, and supports incorporating those rules into the regulations governing administrative dispute resolution under the 340B program.

**(10/11) Consolidation of Claims:**

The Coalition suggests that determination of whether claims of multiple manufacturers or covered entities may be consolidated should lie within the discretion of the decision-making official, taking into account such evidence and arguments as any party may choose to submit going to the issue of whether such consolidation serves the interests of fairness to all parties and economy of resources, particularly where entities with limited resources are involved. In contemplation of this type of issue arising (assuming administrative dispute resolution cases are sufficiently numerous in the 340B program to require appointment of multiple decision officials) a rule should be established that disputes involving the same nexus of material facts concerning the conduct of the same allegedly non-compliant party are to be assigned to the same decision-making official.

**(12) Claims by Organizations Representing Covered Entities:**

The Coalition agrees that representation of covered entities by organizations should be permitted under the circumstances, and based on the prerequisites, outlined in the ANPRM. However, the Coalition also believes organizations should be permitted to initiate and maintain administrative actions for dispute resolution under standards similar to those that are applied in civil litigation to determine the standing of organizations and associations to bring suit on behalf of their members. In other words, we suggest that an association of covered entities should be permitted to initiate dispute resolution as an association on behalf of its members as long as (a) one or more of its members would otherwise be able to initiate the dispute in its own right; (b) the interests at issue in the dispute are germane to the organization's purpose; and (c) the participation of individual members in the proceeding is not necessary to resolution of the dispute.

**(13) Integration of Dispute Resolutions with Other Provisions in the Affordable Care Act:**

It is critically important that the dispute resolution process and the rules established to govern it be carefully integrated with other provisions of the Affordable Care Act. The new statutory responsibilities and authorities of HRSA to independently calculate and monitor 340B prices, as well as to provide covered entities with access to ceiling prices, should be used in support of (and to conserve the parties' expenditure of resources on) discovery in administrative dispute resolution. Statutorily mandated processes for requiring manufacturers to refund overcharges should be applied as part of the remedy for covered entities which prevail in dispute resolution proceedings concerning their allegations of manufacturer overcharging. Civil monetary penalties for overcharging should be imposed pursuant to determinations and investigations triggered by a

variety of different sources, including OPA's spot-checking of manufacturer prices, findings in dispute resolution proceedings, and independent inquiries by the OIG. In achieving this integration, however, it will be important to take into account the fact that some aspects of implementation of the new law will necessarily take longer than others. Thus it may be necessary to put some dispute resolution procedures in place on an interim basis, with a view to revising and enhancing those procedures in the future through more comprehensive integration with other mechanisms and processes required by the new statute.

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The 340B Coalition appreciates the opportunity to submit the above comments. If you have any questions or need additional information, please do not hesitate to contact Staci LeBlanc at (202) 466-8960 or [sleblanc@ftlf.com](mailto:sleblanc@ftlf.com); Roger Schwartz at (202) 296-0158 or [rschwartz@nachc.org](mailto:rschwartz@nachc.org); Mike Glomb at (202) 466-8960 or [mglomb@feldesmantucker.com](mailto:mglomb@feldesmantucker.com); or Bill von Oehsen at (202) 872-6765 or [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org).

Sincerely,

The 340B Coalition