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PUBLIC HOSPITAL PHARMACY COALITION

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

March 23, 1999

VIA FEDERAL EXPRESS

Captain Jimmy J. Mitchell, R. Ph.
Director
Office of Drug Pricing
Bureau of Primary Health Care
4350 East West Highway
East West Towers, Room 10-1A
Bethesda, MD 20814

Dear Captain Mitchell:

The purpose of this letter is to follow up last November's meeting between the Office of Drug Pricing (ODP), the Health Resources and Services Administration (HRSA), and the Public Hospital Pharmacy Coalition (PHPC) concerning several 340B implementation issues that are critical to disproportionate share hospitals (DSHs). The status of each of these issues is addressed below.

(1) **Definition of Patient** – PHPC is preparing a proposal that will build upon: (a) the two-pronged test set forth in ODP's October 24, 1996 guidelines (61 Fed. Reg. 55,156) and (b) the Medicare cost report test outlined in ODP's letter dated September 15, 1998. Consistent with our discussions during the meeting, the proposal will likely add to the definition of patient populations for which the hospitals are legally obligated to provide medical care. It appears that the only unresolved issue is whether the 340B definition of patient should include a narrowly-tailored subset of the population of patients who receive care from faculty practice plans that are closely affiliated with DSH facilities.

(2) **Clinic-Administered Drugs** – In general, hospitals bill clinic-administered drugs on their UB-92 forms either separately or by bundling them with the related services. How the drugs get paid for varies from payor to payor. Based on the November meeting and prior communications with ODP, it is our understanding that clinic-administered drugs are covered under the 340B program as long as they are separately billed on the UB-92 form. I believe that Kathy Lotfi was going to confirm this for us. If necessary, we can arrange a meeting with one or more DSH billing specialists to answer any technical questions that ODP might have.



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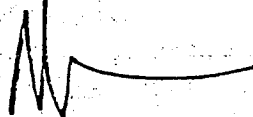
(3) **GPO Exclusion** – HRSA asked PHPC to summarize the practical limits on the GPO exclusion that hospitals need in order to avoid inadvertently violating the law and risking disqualification. HRSA also asked for a legal analysis supporting the government's authority to recognize such limits. Both a description of the requested limits and a legal analysis are enclosed.

(4) **Billing at Acquisition Cost** – At the November meeting, PHPC shared with HRSA and ODP its position that if a given outpatient drug is not subject to a Medicaid rebate, then billing Medicaid at the usual rate (including above acquisition cost) should be permissible since there is no risk of a duplicate discount. This situation exists, we believe, with certain clinic-administered drugs, depending on the state. It is our understanding that Kathy Lotfi was going to discuss this with the Health Care Financing Administration and get back to us.

(5) **Medicaid Carve-Out** – At the end of our meeting, we briefly discussed the issue of whether covered entities are permitted to buy their Medicaid drugs outside of the 340B program. PHPC's position is that this practice – which we call the "Medicaid carve-out" option – is expressly authorized under the 340B statute and should be preserved and made available to covered entities. With respect to pursuing a Medicaid carve-out for a DSH hospital, we believe that the GPO exclusion should not prevent the hospital from buying the carved-out Medicaid drugs through a GPO. A legal analysis of the Medicaid carve-out issue and its relationship to the GPO exclusion is enclosed.

PHPC would like to thank HRSA and ODP for their assistance on the above issues. Please contact us at 202-347-0066 if we have overlooked or misconstrued any aspects of the November meeting. We look forward to your response to the enclosures. In the meantime, we will continue working on item (1) while HRSA and ODP address items (2) and (4).

Sincerely,



William H.E. von Oehsen
Counsel



Ted Slafsky
Director

Enclosures

cc: Kathy Lotfi