DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services

Administrator
Washington, D.C. 20201

November 5, 2015

John C. Martin
Chairman and CEO
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, California 94404

Dear Mr. Martin:

Over the past two years, new pharmaceutical treatments for patients living with hepatitis C virus (HCV) have resulted in higher patient cure rates and more tolerable side effect profiles. Access to promising new treatments is of critical importance, and CMS is committed to making pharmaceutical treatments available to Medicaid beneficiaries when medically necessary. As part of that effort, today CMS issued a reminder to states through a Medicaid Drug Rebate Program Notice regarding coverage requirements and beneficiary access to HCV drugs.

The Centers for Medicare & Medicaid Services (CMS) appreciates the work that manufacturers have done to bring new curative therapies to the market for our consumers, especially when such treatments address a major public health concern such as HCV. Manufacturers also have a role to play in ensuring access and affordability. The agency believes it is important that state Medicaid agencies have access to the lowest available manufacturer prices in the market. Additionally, they should be given the opportunity to participate in discount or value-based purchasing arrangements offered by manufacturers. Therefore, CMS is interested in obtaining information from you about the challenges manufacturers face when offering these types of arrangements to state Medicaid agencies.

Specifically, section 1927 of the Social Security Act (the Act) includes provisions to ensure that the Medicaid rebates for single source and innovator multiple source drugs are based, in part, on a manufacturer's "best price" for each covered outpatient drug. Specifically, section 1927(c)(1)(C) of the Act defines best price, in part, to be the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization (HMO), nonprofit entity, or government entity within the United States. The Act further establishes that best price include cash discounts, free goods contingent on any purchase requirement, volume discounts and rebates (other than rebates under section 1927), which reduce the price available from the manufacturer. CMS believes that some value-based purchasing arrangements may impact best price and would like more information regarding such programs in order to develop future guidance. Toward this end, CMS would like a better understanding of the types of value-based purchasing arrangements, if any, being offered to payers and to state Medicaid agencies, including the following:

- What types of arrangements do you offer to commercial or other government-sponsored health insurance plans that are focused on patient outcomes and enhance access to HCV or other drugs?
- Are these arrangements offered to state Medicaid programs? If so, how are these programs typically structured? If not, what are the challenges in offering these programs to states?

- Can you estimate a monetary value of these arrangements to Medicaid, other government-sponsored or commercial health insurance plans? If so, how? If not, why not?
- What other ideas do you have to assist states in the affordability of these new, unbudgeted pharmaceuticals?

As I said, CMS is committed to ensuring that pharmaceutical treatments are available to Medicaid beneficiaries, when medically necessary. As the agency works with states on these matters, now and in the future, we cannot do that without addressing affordability concerns. Therefore, please provide any information you have on the questions we laid out that will assist us with enhancing Medicaid beneficiary access to needed drugs. CMS would appreciate a response by December 31, 2015. Please contact John Coster, Director, Division of Pharmacy at (410) 786-1121 for follow-up regarding this letter. Thank you for your assistance on this important topic.

Sincerely,

/s/

Andrew M. Slavitt
Acting Administrator