Bayer HealthCare

By Email (info@hbex.ca.gov)

August 6, 2012

The Honorable Diana S. Dooley, Chair
California Health Benefit Exchange
2535 Capitol Oaks Drive, Suite 120
Sacramento, CA 95833

Re: Qualified Health Plan Policies and Strategies to Improve Care, Prevention and Affordability: Options and Recommendations

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Dear Secretary Dooley:

Bayer Healthcare LLC ("Bayer") appreciates the opportunity provided by the California Health Benefit Exchange to comment on Qualified Health Plan Policies and Strategies to Improve Care, Prevention and Affordability: Discussion Draft – Options and Recommendations ("discussion draft").

With more than 16,000 employees in the United States working in our Animal Health, Consumer Care, Medical Care (device business), and Pharmaceutical divisions, Bayer has sought to discover products that will improve human and animal health by diagnosing, preventing and treating diseases. As a specialty pharmaceutical and medical device company, we focus our efforts where we can have the most beneficial impact on the lives of those who depend on our century of experience in research and development. Our efforts, however, require that patients have meaningful access to the pharmaceuticals and medical devices that we develop, and Bayer is committed to working with the California Health Benefit Exchange to achieve the goal that every Californian has the health insurance coverage necessary to live a healthy and productive life.

I. Summary and Overview of Comments

Bayer commends the California Health Benefit Exchange ("Exchange") for serving as a pioneer in the development of policies that will establish the Exchange and ensure that all Californians gain quality, affordable health care coverage. As one of the first to develop these policies since enactment of the Affordable Care Act, the Exchange is likely to serve as a benchmark for other state exchanges, and Bayer would like to offer comments on the Exchange staff's recommendations relating to formulary requirements for qualified health plans ("QHPs"). In summary:

- Bayer is generally supportive of the Exchange staff's recommendation to require QHPs to cover a minimum of two drugs per therapeutic

area, which is consistent with Medicare Part D standards and encourages the Exchange board to approve this recommendation;

- Bayer encourages the Exchange Board to institute a Protected Class of Drugs Policy—consistent with Medicare Part D, which would require that QHPs cover "all or substantially all" drugs within a category or class of drugs that, if restricted to patients, would constitute a "major or life threatening clinical consequence"[1]; and

- Bayer encourages the Exchange to require health plans participating in the state exchanges to provide sufficiently detailed information to Navigators and patients on drug coverage, preventive and wellness, and other benefits to help facilitate informed choice of a health plan.

II. Formulary Recommendation Requiring Two Drugs Per Therapeutic Class or Category

Bayer applauds the Exchange staff for recognizing the importance of protecting physician and patient drug choice by requiring health plans to provide coverage for two drugs per therapeutic area ("two drug benefit"). As one of the ten benefit categories of coverage required by the Affordable Care Act ("ACA"), prescription drug coverage is among the most important plan benefits to America's patients and their physicians. Accordingly, patients are likely to determine, in part, whether to participate in an exchange on the basis of how well a QHP's prescription drug coverage reflects their needs. In support of that process, the Exchange staff should make sure that current and prospective patients are easily able to access information about the availability of specific medications in a health plan, much like that already facilitated for the Medicare Part D Plan Finder.[2] By requiring a two drug benefit by QHPs, which is consistent with Medicare Part D, the Exchange is likely to increase consumer interest and confidence in the QHPs available on the Exchange.

Moreover, better prescription drug coverage may help to address the problem of patient non-adherence to prescribed drug treatments. A Kaiser Family Foundation report shows that even when patients have prescription drug coverage at least 22 percent of them will not fill the prescription, despite their physician's advice.[3] The two drug benefit, which is more robust than CMS has proposed thus far, would help to effectuate a physician's best advice for a patient and build patient confidence in the affordability of a prescribed course of treatment.

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[1] *See* 42 USC § 1395w-104(b)(3)(G); Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), Pub. L. No. 110-275 § 176 (2008).
[2] *See* Medicare Plan Finder, Medicare.gov, *available at* https://www.medicare.gov/find-a-plan/questions/home.aspx.
[3] Kaiser Family Foundation, *Prescription Drug Trends*, May 2010, *available at* http://www.kff.org/rxdrugs/upload/3057-08.pdf.

For these reasons, Bayer strongly encourages the Exchange board to approve the staff recommendation that "benefit plans offered in the Exchange. . . meet at least the Medicare Part D minimum standard of at least two drugs per class or category."

III. Protected Classes of Drugs

Building on a previous policy that certain classes and categories of drugs are vital to the health and well-being of individuals facing particular diseases or disorders, Congress established through the ACA six categories and classes of drugs of clinical concern for which Medicare Part D plans must provide coverage.[4] This Protected Classes of Drugs Policy ("Protected Classes Policy") requires that Medicare Part D plans "include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes."[5] The Protected Classes Policy serves as a recognition that when certain categories or classes of drugs are restricted to patients, there may be a "major or life threatening clinical consequence."[6] CMS has also recognized that ensuring coverage of all or substantially all drugs within the protected classes would help "ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[7]

Despite the arguments by Congress and, even CMS itself, to support the Protected Classes Policy in the Medicare Part D context, CMS has chosen not to extend the policy,[8] at present, to the Essential Health Benefits that QHPs must provide. Nonetheless, the ACA permits the Exchange to require that health plans offer additional benefits, beyond that required by the statute or CMS. As one of the first exchanges to establish its QHP requirements, the Exchange has the important opportunity to set a benchmark for prescription drug coverage that will help to ensure access to affordable, high quality care in California and across the nation.

While Bayer strongly supports the application of the Protected Classes Policy to Medicare Part D patients, it is equally important to all patients who suffer from diseases or conditions applicable to the six classes, regardless of

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[4] Affordable Care Act, § 3307.
[5] Center for Medicare and Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6, Sec. 30.2.5 – Protected Classes, *available at* https://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf.
[6] MIPPA § 176.
[7] Center for Medicare and Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6, Sec. 30.2.5 – Protected Classes.
[8] Center for Consumer Information and Insurance Oversight, Essential Health Benefits Bulletin, Center for Medicare and Medicaid Services, Dec. 16, 2011, *available at* http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

whether their prescription drug coverage comes from Medicare Part D or through a health plan offered on the Exchange. To make the choice not to apply the Protected Classes Policy, which Congress has recognized as vitally important to certain populations, has the effect of making state exchange health plans of second-class status in comparison to their Medicare Part D counterparts.

Bayer strongly urges the Exchange board to adopt the Protected Classes Policy as a requirement for QHPs. That policy should require that QHPs cover the six categories required for Medicare Part D and such other categories of drugs that the Exchange determines, if not covered, would present a "major or life threatening clinical consequence."

IV. Providing Health Plan Drug Coverage Data to Patients

Bayer encourages the Exchange to require health plans participating in state exchanges to provide a sufficient level of detail to Navigators and consumers to assist with plan selection. As reflected in the recent *New York Times* article "Navigating the Healthcare Maze", many consumers have difficulty making effective comparisons between plans, in part because benefit information is not provided at a sufficiently detailed level.[9] Additional detail on drug coverage, preventive and wellness, and other benefits will help patients make informed selections of the health plan that best suits their individual needs.

Examples of the types of information that should be available to patients includes:

- the specific services covered within a benefit category;
- any copay, coinsurance, or other cost sharing associated with a drug or service;
- any requirement that prior authorization be received for a drug or service;
- how frequently those prior authorizations are granted;
- a description of other plan policies that would restrict or delay coverage of a drug or service; and
- a description of appeals and/or exceptions procedures.

These types of data points will help patients make informed decisions about the health plan that best fits their individual circumstances. Accordingly, Bayer encourages the Exchange to require health plans to provide detailed benefit information to Navigators and consumers for use during health plan selection.

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[9] Abby Goodnough, Navigating the Healthcare Maze, *New York Times* (June 12, 2012), *available at* http://www.nytimes.com/2012/06/13/us/navigating-the-health-care-maze.html?_r=1.

Bayer appreciates the opportunity to comment on the discussion draft and looks forward to working with the Exchange to ensure that all Californians have affordable, quality health insurance care coverage.

Sincerely,

Raymond Frost