



Denver Metropolitan Affiliate
1835 Franklin Street, Denver, Colorado 80218
303-744-2088, Helpline 1-877-GO-KOMEN
www.komendenver.org

Submitted electronically to: ehb@dora.state.co.us

August 5, 2012

Colorado Division of Insurance
Department of Regulatory Agencies (DORA)
1560 Broadway, Suite 850
Denver, CO 80203

Re: Essential Health Benefits Benchmark Selection

Dear Staff of the Governor's Office, the Division of Insurance and the Colorado Health Benefit Exchange:

The Denver Metropolitan Affiliate of Susan G. Komen for the Cure® (Komen Denver) appreciates the opportunity to comment on Colorado's Benchmark Selection Process.

Susan G. Komen for the Cure® is the country's largest grassroots network of breast cancer survivors and advocates. At the heart of Komen's mission is saving lives, empowering people, ensuring quality care, and energizing science to find the cures. Komen Denver continually strives to meet this mission through education, grant making and fundraising. The Denver Affiliate serves 19 counties and has granted more than \$28 million for breast health services and education to medically underserved populations within the 19-county service area.

The Affordable Care Act (ACA) requires the U.S. Department of Health and Human Services (HHS) to define an "essential health benefits" (EHB) package that non-grandfathered plans will be required to offer both on and off the Exchanges to individuals and small employers purchasing insurance; certain Medicaid expansion plans known as benchmark or benchmark equivalent plans; and state Basic Health Programs.¹ The ACA also specifies 10 general

¹ See § 1302 of the ACA, Pub. L. 111-148, as amended by Pub. L. 111-152.



Denver Metropolitan Affiliate
1835 Franklin Street, Denver, Colorado 80218
303-744-2088, Helpline 1-877-GO-KOMEN
www.komendenver.org

categories of benefits that must be included in the essential health benefits package. These include: ambulatory patient services; emergency services; hospitalizations; maternity and newborn care; mental health and substance use disorder services including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; preventive and wellness services; chronic disease management; and pediatric services including oral and vision care.²

The Center for Consumer Information and Insurance Oversight (CCIIO), on December 16, 2011, issued an informational Bulletin to inform the public about HHS' regulatory approach to defining EHB. In the Bulletin, CCIIO stated that HHS intends to propose adopting a benchmark plan approach. Under this approach, the Bulletin explains, a benchmark plan chosen by a state will serve as the standard for plans (and the EHB package of benefits and services) offered in that State. In selecting a benchmark health insurance plan, a state may choose from the following options: (1) the largest plan by enrollment in any of the three largest small group insurance products in the State's small group market; (2) any of the three largest small group plans in the state by enrollment; (3) any of the three largest federal employee benefit health plan options by enrollment; or (4) the largest insured non-Medicaid HMO plan offered in the state's commercial market by enrollment.³

Komen Denver respectfully offers the following comments on Colorado's process for selecting a benchmark plan:

Providing Coverage in Required Categories

The benchmark options cover the 10 categories specified by the statute from a very high vantage point. Yet, additional plan details are needed to determine whether the coverage in each of these

² See § 1302(b)(1) of the ACA, Pub. L. 111-148, as amended by Pub. L. 111-152.

³ *Essential Health Benefits Bulletin*, Center for Consumer Information and Insurance Oversight, 9, Dec. 16, 2011, available at http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.



Denver Metropolitan Affiliate
1835 Franklin Street, Denver, Colorado 80218
303-744-2088, Helpline 1-877-GO-KOMEN
www.komendenver.org

categories are adequate. We are particularly concerned that HHS is considering allowing substitutions based on actuarial value, including across categories, because we believe this has potential for abuse and could allow the EHB package to include inadequate items and services in certain benefit categories.

The EHB package must offer those with life-threatening and/or chronic illnesses adequate coverage at affordable prices. Regardless of the benchmark selected by Colorado, we believe the state should require plans to commit to preventing substitutions that could deter those with complex medical needs from enrolling.

The benchmark option that Colorado selects and any substitutions that may then be necessary to meet the EHB statutory requirements should also be subject to public comment and oversight to ensure that the plans in that State will meet the ACA requirement that the EHB package “reflect an appropriate balance among the categories described in the subsection, so that the benefits are not unduly weighted toward any category.”

Balancing Comprehensiveness and Affordability

Along with the EHB categories of benefits and services that will be covered by the plan that Colorado chooses under the benchmark option, the comprehensiveness and affordability of coverage will also be impacted by several other important factors. Many of the health insurance plans that could be chosen under the benchmark approach utilize “medical necessity” determinations to make decisions about allowing coverage of certain important services, like genetic testing. Policies with respect to these determinations can vary from plan to plan. Therefore, in order to protect patients, it will be critical to determine how this term is defined, who makes the medical necessity determination, and to ensure a transparent process, and adequate process for appeals.



Denver Metropolitan Affiliate
1835 Franklin Street, Denver, Colorado 80218
303-744-2088, Helpline 1-877-GO-KOMEN
www.komendenver.org

The extent to which patients may be denied access to important benefits and services will also depend on a number of other factors such as how the formularies will be updated to include new and improved therapies and the difficulty and duration of any appeals or prior authorization processes. We are concerned, in particular, with whether and how inside limits on coverage of particular items and services will be carried over. If plans can make a substitution actuarially equivalent to these inside limits, we are concerned that this could adversely impact coverage of essential benefits.

Prescription Drug Coverage

The prescription drug category is particularly hard to assess without detailed formulary information, which is not included in the plan summaries or comparisons that can be easily accessed by the public. We believe there is a need for further guidance from HHS regarding how the formulary of the benchmark option selected would translate to the EHB package and what happens if it is in the form of a rider. In order to determine the plan that would be best for breast cancer patients, we would need to be assured that critical treatments for breast cancer patients are covered, including specialty drugs, injectibles and accepted off-label drugs.

Additionally, we believe the standard described in the CCIIO informational Bulletin issued on December 16, 2011, which states that formularies would only be required to include at least one drug in each category or class, falls short of Medicare's requirements and is likely to result in inadequate coverage.⁴ While we recognize that several of the benchmark options cover more than one drug per class or category of drugs, we want to ensure that this more comprehensive coverage is required to be in the benchmark plan that is used to define the EHB package. Plans that have to cover EHB must be required to cover all the drugs in each class or category that are covered by the benchmark option selected.

⁴ *Essential Health Benefits Bulletin*, Center for Consumer Information and Insurance Oversight, 12-13, Dec. 16, 2011, available at http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.



Denver Metropolitan Affiliate
1835 Franklin Street, Denver, Colorado 80218
303-744-2088, Helpline 1-877-GO-KOMEN
www.komendenver.org

In order for patients to have access to quality cancer care, patients must have access to the most appropriate therapies for their diseases. If only one drug in a class or category is available, cancer patients will be limited in their covered treatment options and may not have access to the most effective treatments. Further, if that one covered drug is not optimal for a particular patient, adverse side effects may result. Therefore, Komen believes strongly that, in order to ensure access to standard of care treatments, all appropriate therapies must be covered, and more than one drug in a class must be available.

We believe it is critical that commonly prescribed off-label uses for breast cancer treatment are included in the essential health benefits package. Off-label anti-cancer drugs are currently covered under Medicare Part D, if the use is supported in designated compendia. We believe that the benchmark selected should cover accepted off-label uses to treat cancer and specialty drugs, including injectables and biologics.

State-Mandated Benefits

We are concerned that if Colorado does not select one of the benchmark plan options that includes state benefit mandates (Options A, B, E, and F), requirements to cover critical elements of cancer care, including parity coverage of standard of care cancer treatments, such as oral chemotherapy, will be vulnerable. If it is likely that defraying the cost will lead to repealing these requirements, we urge the state to consider options that would prevent such repeal or that would ensure that they are otherwise included in the benchmark selected.

Access to Clinical Trials

Komen would like to urge Colorado to choose a benchmark plan that provides comprehensive coverage of clinical trials. We are aware that the ACA section 1201 amended the Public Health Service Act (PHSA) to include Section 2709, a section on clinical trials coverage. Section 2709



Denver Metropolitan Affiliate
1835 Franklin Street, Denver, Colorado 80218
303-744-2088, Helpline 1-877-GO-KOMEN
www.komendenver.org

establishes new safeguards to protect patient access to clinical trials by requiring group health plans and insurance issuers to cover routine patient care costs incurred when individuals enroll in clinical trials for the prevention, detection, or treatment of cancer and other life-threatening diseases.

We believe the benchmark plan that is selected for purposes of the EHB package should apply these protections to all individual and small group plans. Therefore, we support choosing a plan subject to the state mandate to cover routine costs associated with clinical trials or that independently provides this coverage. Any restrictions to clinical trials coverage in the benchmark option selected should not create a barrier to access and participation in clinical trials by excluding coverage of routine costs or services that are not covered by the sponsor of the clinical trial. Additionally, we believe the benchmark selected should cover reasonable and necessary items and services used to diagnose and treat complications associated with clinical trial participation.

Genetic Evaluation and Counseling

Based on our research, several of the potential benchmark plans in Colorado only cover genetic testing for inherited susceptibility for breast cancer if it is deemed medically necessary. This raises the issue described above that medical necessity is not defined by statute, nor is there a standard process for determining medical necessity. Even if the carrier providing the benchmark option selected provides adequate coverage of genetic testing based on their process for determining the medical necessity of this benefit, there are no assurances how this will translate when other plans adopt the EHB package. Unless further guidance is provided, each carrier will retain its distinct process for determining medical necessity, even if this could negatively impact coverage of an important benefit that should be included in the benchmark option selected.

The ACA requirement that health plans cover, without cost-sharing, preventive services with the U.S. Preventive Services Task Force (USPSTF) rating of A or B provides assurances regarding



Denver Metropolitan Affiliate
1835 Franklin Street, Denver, Colorado 80218
303-744-2088, Helpline 1-877-GO-KOMEN
www.komendenver.org

coverage of BRCA genetic counseling and evaluation for women with family histories associated with increased risk, but does not assure coverage of the testing itself.⁵ We could only support a benchmark option that covers the BRCA test for women whose family history is associated with increased risk for deleterious mutations in the BRCA1 or BRCA2 genes.

Preventive and Wellness Services and Chronic Disease Management

In addition to covering screening mammography for women every 1-2 years for women aged 40 and older, we believe the plan that is chosen to be Colorado's benchmark plan should also cover routine mammography for high risk individuals and advanced imaging tests (CT, MRI, PET scans) as recommended by the individual's health care provider.

Conclusion

The EHB package will establish standards that will determine the extent to which patients in Colorado will have access to health care services. Therefore, it is critical that the State take into account these considerations when selecting among plan options to implement the proposed benchmark approach. Komen appreciates the opportunity to comment on Colorado's EHB benchmark selection process and we look forward to working with you to ensure that it provides adequate coverage for patients with breast cancer.

Sincerely,

Hollen M. Ferrendelli, President, Komen Denver Board of Directors

Michele Ostrander, Executive Director, Komen Denver

Joanne Vermeulen, Director of Grants & Public Policy, Komen Denver

*For inquiries contact Joanne Vermeulen at jvermeulen@komendenver.org, 303-744-2088 ext. 305

⁵ See <http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrgen.htm>.