We are very concerned that VBID can inadvertently be used to block consumer’s access to preventive care without cost sharing (as required under PHS Act section 2713) if not accompanied by the following important safeguards.

1) The relevant evidence-base for frequency, method, treatment, or setting under VBID should first and foremost be the Supporting Documents published in conjunction with the release of a United States Preventive Services Task Force (USPSTF) recommendation. Although the final Recommendation may be very succinct, there is generally a strong body of evidence supporting that recommendation. In many cases there are more detailed graded recommendations incorporated into the body of evidence supporting the macro recommendation. For example, The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. The AHRQ supporting documents include: 15 A or B recommendations specific to Screening and Counseling, 12 A or B recommendations specific to Medication and 3 A or B recommendations specific to Systems.

2) Medical management must not permit the absolute exclusion of any A or B recommendation.
For example, plans must still offer all A recommended FDA-approved pharmacotherapies even if limitations based on medical management techniques are permitted. If supported by the evidence, medical management may incorporate annual limitations, but should not be permitted to include lifetime limitations. Lifetime limitations run counter to Patient Protection Affordable Care Act’s prohibition on lifetime benefit maximums and should not be permitted unless the USPSTF recommendation explicitly incorporates such a limitation. Although several A and B recommendations include age limits or annual limits, only abdominal aortic aneurysm screening for men recommends a one-time screening.

Attachments

EBSA-2010-0054-DRAFT-0008.1: Comment on FR Doc # 2010-32612
Comments on Interim Final Regulations Regarding Use of Value-Based Insurance Design and Medical Management in Implementing USPSTF A and B Recommended Preventive Services

On July 19, 2010 the Federal government published the “Interim Final Rules... Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act” (the Rule). The Rule requires group health plans and health insurers to cover certain preventive health services with no cost-sharing for such services. The Rule does not apply to grandfathered plans and is generally applied to plan years beginning on or after September 23, 2010.

Required Preventive Health Services
- Evidence-based items or services rated A or B in the current recommendations of the United States Preventive Services Task Force (“USPSTF”).
- Immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (“ACIP”).
- Preventive care and screenings for infants, children, and adolescents.
- Additional preventive care and screenings for women as provided for by the HRSA.
- Recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention, excluding the recommendations issued in or around November 2009.

Medical Management and Coverage and Cost-Sharing for Out-of-Network
The Rule provides that if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer may use reasonable medical management techniques to determine any coverage limitations. The use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines for coverage of specific items and services where cost sharing must be waived. Thus, a plan or issuer may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available without cost-sharing requirements to the extent not specified in a recommendation or guideline.

The Rule clarifies that if a plan or insurer has a network of providers, the plan or insurer:
- Is not required to provide coverage for preventive services delivered by an out-of-network provider.
- May impose cost-sharing for preventive services delivered by an out-of-network provider.

Finally, the Rule asks for input regarding the use of Value-Based Insurance Design (VBID). The preamble recognizes the important role that VBID can play in promoting the use of appropriate preventive services. What follows is input regarding two critical aspects of VBID relative to preventive services.

Comments and Recommendations
The Rule relies on two key points:
1. There is an accepted evidence-base to determine frequency, method, treatment or setting
2. Reasonable medical management techniques are well established and accepted/implemented consistently by health plans and insurers.

We accept the role that VBID can play in promoting consumer use of specific services. We also recognize the practical value of providing health plans the ability to use medical management to
determine frequency, method, treatment or setting for preventive services to the extent that the USPSTF does not specify those conditions. However, we are very concerned that VBID can inadvertently be used to block consumer’s access to preventive care without cost sharing (as required under PHS Act section 2713) if not accompanied by the following important safeguards.

1. Evidence-base for Determining Frequency, Method, Treatment or Setting
   - The relevant evidence-base for frequency, method, treatment, or setting under VBID should first and foremost be the Supporting Documents published in conjunction with the release of a USPSTF recommendation.
     - Although the final Recommendation may be very succinct, there is generally a strong body of evidence supporting that recommendation. In many cases there are more detailed graded recommendations incorporated into the body of evidence supporting the macro recommendation.
     - For example, the tobacco recommendation is very succinct but includes significant supporting documentation and additional detailed A and B recommendations:

   **Tobacco Use Counseling: Non-pregnant adults** _A recommendation, April 2009_

   The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.

   The AHRQ Supporting Documents include:
   - 15 _A_ or _B_ recommendations specific to Screening and Counseling
   - 12 _A_ or _B_ recommendations specific to Medication
   - 3 _A_ or _B_ recommendations specific to Systems

2. Medical Management to Justify VBID
   - Medical management must not permit the absolute exclusion of any A or B recommendation.
     - For example, plans must still offer all A recommended FDA-approved pharmacotherapies even if limitations based on medical management techniques are permitted.
   - If supported by the evidence, medical management may incorporate annual limitations, but should not be permitted to include lifetime limitations. Lifetime limitations run counter to PPACA’s prohibition on lifetime benefit maximums and should not be permitted unless the USPSTF recommendation explicitly incorporates such a limitation.
     - Although several A and B recommendations include age limits or annual limits, only abdominal aortic aneurysm screening for men recommends a one-time screening.