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The Challenging Crosswalk Between USPSTF Recommendations and Coverage Considerations for Payers and Providers

Overview and Case Studies

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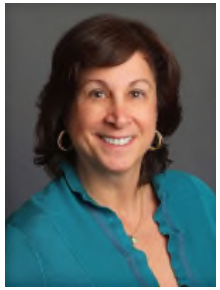

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Overview of Considerations for Payers and Providers

Coverage of Preventive Services

Considerations for Private Health Plans/Payers

- Group health plans/payers (including insured and self-funded employer-sponsored plans) may embrace coverage of preventive services, but requirements in the Affordable Care Act ("ACA") now dictate certain preventive services that must be covered
  - What are the private payer rules for coverage of preventive services, including preventive services with an "A" or "B" rating from the United States Preventive Services Task Force ("USPSTF")?
  - USPSTF recommendations do not always speak in terms of insurance coverage language
  - Consequently, private payers must translate the USPSTF recommendations into coverage policies describing the frequency, method, treatment, eligible providers, and setting for a covered preventive service with an "A" or "B" rating

Coverage of Preventive Services

Compliance Challenges for Private Health Plans/Payers

- Health plans/payers must:
  - Monitor new USPSTF recommendations for preventive services with an "A" or "B" rating
  - Understand when a USPSTF recommendation must be translated into a new coverage policy
    - Plan/policy years starting on or after the date that is one year after the effective date of the USPSTF recommendation
  - Identify where there is discretion to determine the scope of coverage and the providers who can furnish the covered preventive services
  - Determine how to justify coverage policies and document compliance with statutory and regulatory obligations related to mandatory plan coverage of preventive services
    - E.g., memo to file documenting consideration of USPSTF recommendation, evaluation of the evidence, application of reasonable medical management techniques, etc.

Coverage of Preventive Services

Considerations for Providers

- Providers should understand what the rules are for plan mandatory coverage of preventive services
  - Providers should monitor new USPSTF recommendations for preventive services with an "A" or "B" rating in order to identify opportunities
    - Are you a provider who could deliver the preventive service, as described in the USPSTF recommendation?
    - Does coverage extend to services provided by non-traditional providers or in non-traditional settings?
      - E.g., does the USPSTF recommendation address service delivery by provider-based programs or local, individual community-based programs?
      - Does the USPSTF recommendation allow for covered services to be provided outside of the typical physician office visit format (e.g., through the use of community-based providers, remote monitoring, technology-based solutions, etc.)?
    - Would a corporate entity be able to provide the service, or only individual professionals?

Coverage of Preventive Services

Case Study Overview / Specific Actions Required

Tobacco Cessation Counseling and Interventions	
Coverage Required	Plan/policy years beginning on or after September 23, 2010
Required Services	Defined in DOL FAQ (including screening, counseling sessions, and medication)
Eligible Providers	Defined in Public Health Service Clinical Guidelines (such as “various primary care clinicians” and “staff”, “health system-based tobacco coordinator”, or “community resources”)

Obesity/Overweight Intensive Behavioral Counseling	
Coverage Required	Plan/policy years beginning on or after June 26, 2013 (Obesity) Plan/policy years beginning on or after August 26, 2015 (Overweight + CVD Risk)
Required Services	Flexibility to define scope of coverage, based on language in USPSTF recommendation
Eligible Providers	Flexibility to identify eligible providers, including community-based and non-traditional providers (such as DPP providers)

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Background

Introduction to the USPSTF

Creation / Organizational Structure

- The USPSTF was created in 1984 as an initiative of the U.S. Public Health Service
  - It was created as a government advisor with the mission of assessing the clinical utility of preventive health measures and issuing **non-binding recommendations** about which measures doctors should incorporate into routine medical care
- Since 1998, the USPSTF has been supported by the Department of Health & Human Services Agency for Healthcare Research & Quality ("AHRQ")
  - AHRQ is authorized to convene the USPSTF and to provide ongoing research, technical, administrative, and dissemination support for the USPSTF's operation
  - Despite AHRQ's support, the USPSTF is an **independent entity**
- The USPSTF previously was funded by the AHRQ via the Prevention and Public Health Fund, which was established by the ACA
  - In FY 2015, AHRQ did not receive funding from this Fund to support the USPSTF and instead used funds from the Prevention/Care Management Research portfolio (in which the USPSTF is incorporated)

Introduction to the USPSTF

Mission / Principle Activities

- The USPSTF is charged with **making recommendations to primary care providers** about clinical preventive services by comprehensively and systematically reviewing evidence of prioritized clinical preventive services
  - The recommendations address clinical preventive services for adults and children, and include screening tests, counseling services, and preventive medications
- Consideration Cycles
  - In past years, the USPSTF generally has selected one or two new topics a year for which to evaluate the evidence and develop a recommendation
    - Development of a recommendation statement by the USPSTF from a newly nominated topic takes approximately 2-3 years
  - Each year, the USPSTF submits a report to Congress that identifies critical evidence gaps in research related to clinical preventive services and recommends priority areas that deserve further examination

Introduction to the USPSTF

Participation / Responsibilities

- The USPSTF consists of an independent panel of 16 medical experts in primary care prevention, including internists, pediatricians, family physicians, gynecologists/obstetricians, nurses, and health behavior specialists
  - Each year, the Director of the AHRQ appoints new members to serve 4-year terms and replace those who are completing their service
  - Interested individuals can self-nominate or organizations and individuals may nominate one or more persons qualified for membership
  - The members are all volunteers and AHRQ looks to maintain balance in member expertise
- Members are responsible for prioritizing topics, designing research plans, reviewing and commenting on systematic evidence reviews, discussing and making recommendations on preventive services, reviewing stakeholder comments, drafting final recommendation documents, and participating in workgroups on specific topics and methods

Overview of Preventive Services Recommendations

A, B, C, and D Ratings

- Ratings
  - A: USPSTF recommends the service. There is high certainty that the net benefit is substantial.
  - B: USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
  - C: The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.
  - D: The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.

Overview of Preventive Services Recommendations

A, B, C, and D Ratings

- Levels of Certainty
  - High: The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
  - Moderate: The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as:
    - The number, size, or quality of individual studies.
    - Inconsistency of findings across individual studies.
    - Limited generalizability of findings to routine primary care practice.
    - Lack of coherence in the chain of evidence.
    - As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.

Overview of Preventive Services Recommendations

Selecting Topics for Review

- Topics for USPSTF recommendations may be submitted at any time by anyone
  - Topic recommendations may be made by suggesting a new preventive service topic, supported by evidence that has been published in a peer-reviewed journal, or by recommending reconsideration of an existing topic
    - There is a 5-year cycle of review during which the USPSTF may reconsider a recommendation
    - Reconsideration may stem from research published after a recommendation's release or changes in the issue
  - For more information on how to nominal a topic for recommendation, *see* http://www.uspreventiveservicestaskforce.org/Page/Name/nominating-recommendation-statement-topics

Overview of Preventive Services Recommendations

Selecting Topics for Review

- Nominated topics must be within the scope of the USPSTF
- Topics must:
  - Be related to a preventive service that is meant to avoid the development of disease (primary prevention) or identify and treat an existing disease before it results in significant symptoms (secondary prevention);
  - Be relevant to primary care; and
  - Address a disease with a substantial health burden.
- Topics that meet these criteria are prioritized according to:
  - Prevention and primary care;
  - Importance for public health;
  - Potential impact of the recommendation; and
  - Whether there is new evidence that may change a current recommendation.

Overview of Preventive Services Recommendations

Determining a Rating

- Research Plan – A draft is developed by the USPSTF and researchers from an Evidence-based Practice Center ("EPC") that includes key questions and target populations for the topic
  - The research plan is posted online for four weeks for comment; comments are reviewed and considered and the plan is finalized and posted online
- Draft Evidence Review and Recommendation Statement – EPC researchers gather, review, and analyze evidence from studies published in peer-reviewed scientific journals. This evidence is summarized and a draft evidence review is developed. The USPSTF discusses the evidence review and determines the effectiveness of the service by weighing the potential benefits and harms. The USPSTF develops a draft recommendation statement.
  - Both the evidence review and recommendation statement are posted for four weeks for public comment
- Final Evidence Review and Final Recommendation Statement – All comments are reviewed and considered. The evidence review and recommendation statement are finalized and posted online. The recommendation statement and a final evidence summary are published in a peer-reviewed scientific journal.

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Application of USPSTF Recommendations to Coverage

Intersection of USPSTF Recommendations with Coverage

Growth of USPSTF Authority Over Time

- (1984) – The USPSTF began as governmental advisors issuing nonbinding recommendations
- (2008) – The process for Medicare's coverage of individual preventive services changed to a national coverage determination process – run by Medicare but influenced by USPSTF recommendations
- (2010) – Section 2713 of the Public Health Service Act ("PHSA"), as added by Section 1001 of the ACA, requires **"group health plans" (insured and self-funded) and "health insurance issuers" offering group or individual health insurance coverage** to provide coverage and not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) for evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the USPSTF

Intersection of USPSTF Recommendations with Coverage

Private Payers

- What is a "group health plan"?
  - An employee welfare benefit plan established or maintained by an employer or by an employee organization (such as a union), or both, to the extent that the plan provides medical care to employees or their dependents directly or through insurance, reimbursement or otherwise. ERISA § 733(a) and 29 CFR 2590.701-2.
    - E.g., employer-sponsored group health insurance plan, self-insured health plan, self-insured medical reimbursement plan
- What is a "health insurance issuer"?
  - An insurance company, insurance service, or insurance organization, (including a health maintenance organization), that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance. ERISA § 733(b)(2) and 29 CFR 2590.701-2.
    - E.g., large and small group health insurance plan, individual insurance plan

Intersection of USPSTF Recommendations with Coverage

USPSTF A/B Rated Preventive Services (as of October 2014)

Release Date of Current Recommendation	Topic	Description	Grade
September 2014*	Chlamydia screening: women	The USPSTF recommends screening for chlamydia in sexually active women age 24 years or younger and in older women who are at increased risk for infection.	B
September 2014*	Gonorrhea screening: women	The USPSTF recommends screening for gonorrhea in sexually active women age 24 years or younger and in older women who are at increased risk for infection.	B
September 2014*	Sexually transmitted infections counseling	The USPSTF recommends intensive behavioral counseling for all sexually active adolescents and for adults who are at increased risk for sexually transmitted infections.	B
September 2014	Preeclampsia prevention: aspirin	The USPSTF recommends the use of low-dose aspirin (81 mg/d) as preventive medication after 12 weeks of gestation in women who are at high risk for preeclampsia.	B
August 2014*	Healthy diet and physical activity counseling to prevent cardiovascular disease: adults with cardiovascular risk factors	The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.	B
June 2014*	Abdominal aortic aneurysm screening: men	The USPSTF recommends one-time screening for abdominal aortic aneurysm by ultrasonography in men ages 65 to 75 years who have ever smoked.	B
May 2014*	Dental caries prevention: infants and children up to age 5 years	The USPSTF recommends the application of fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption in primary care practices. The USPSTF recommends primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is fluoride deficient.	B
May 2014	Hepatitis B screening: nonpregnant adolescents and adults	The USPSTF recommends screening for hepatitis B virus infection in persons at high risk for infection.	B
January 2014	Gestational diabetes mellitus screening	The USPSTF recommends screening for gestational diabetes mellitus in asymptomatic pregnant women after 24 weeks of gestation.	B

- There are currently 55 preventive services with an “A” or “B” rating from the USPSTF
- The full list available at http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/

Intersection of USPSTF Recommendations with Coverage

USPSTF and Benefits / Coverage Mandates

- Who: **private payer coverage** offered through "group health plans" and "health insurance issuers" must include preventive services with an "A" or "B" rating from the USPSTF
- When: private payers must add coverage for these preventive services in the **first plan year/policy year beginning one year after the effective date** of the new recommendation or guideline
- What: private payers have some flexibility in how they determine the scope of coverage for these preventive services
  - 45 C.F.R. § 147.130(a)(4) expressly states that the requirement that health insurers and group health plans pay for such services with no cost-sharing does not prevent them from using "reasonable medical management techniques" to control costs
    - This includes determining the frequency, method, treatment, or setting for a covered preventive service to the extent the preventive service, itself, does not specify the scope of the service

Intersection of USPSTF Recommendations with Coverage

USPSTF and Benefits / Coverage Mandates

- Additional flexibilities include:
  - In-network v. Out-of-network
    - 45 C.F.R. § 147.130(a)(3) expressly states that "[n]othing in this section requires a plan or issuer that has a network of providers to provide benefits for [covered preventive services] … that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for [covered preventive services] that are delivered by an out-of-network provider."
  - Coverage for Treatment
    - Preventive services do not include treatment for conditions diagnosed through the preventive service or screening: "[a] plan or issuer may impose cost-sharing requirements for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service."

Intersection of USPSTF Recommendations with Coverage

Implementing Coverage of USPSTF A/B Rated Preventive Services

- Translating Recommendations into Covered Benefits
  - USPSTF evidence review and recommendations are conducted and written for primary care providers so that the providers may revise and incorporate these recommendations into their practices
    - The recommendations generally are not written in the context of payer coverage
  - The ACA has applied USPSTF recommendations to payer coverage
  - Health plans and providers need to understand how to translate these recommendations for the practice of primary care into payer benefits/insurance coverage plans and policies

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Case Studies

Case Studies

Implementing Coverage of USPSTF A/B Rated Preventive Services

- Translating Recommendations into Coverage Plans
  - Tobacco Cessation (Adults and Pregnant Women) – "A" recommendations
    - The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products ***(April 2009)***
    - The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke ***(April 2009)***
  - Obesity/Overweight Behavioral Counseling (related to obesity and CVD risk reduction) – "B" recommendations
    - The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease ("CVD") risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention ***(August 2014)***
    - The USPSTF recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index (BMI) of 30 kg/m2 or higher to intensive, multicomponent behavioral interventions. ***(June 2012)***

Case Studies

Coverage of Tobacco Cessation Interventions

COUNSELING AND INTERVENTIONS TO PREVENT TOBACCO USE AND TOBACCO-CAUSED DISEASE IN ADULTS AND PREGNANT WOMEN: CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	Adults Age ≥18 Years	Pregnant Women of Any Age
Recommendation	Ask about tobacco use. Provide tobacco cessation interventions to those who use tobacco products.	Ask about tobacco use. Provide augmented pregnancy-tailored counseling for women who smoke.
	Grade: A	Grade: A
Counseling	The "5-A" framework provides a useful counseling strategy: 1. Ask about tobacco use 2. Advise to quit through clear personalized messages 3. Assess willingness to quit 4. Assist to quit 5. Arrange follow-up and support Intensity of counseling matters: brief one-time counseling works; however, longer sessions or multiple sessions are more effective. Telephone counseling "quit lines" also improve cessation rates.	
Pharmacotherapy	Combination therapy with counseling and medications is more effective than either component alone. FDA-approved pharmacotherapy includes nicotine replacement therapy, sustained-release bupropion, and varenicline.	The USPSTF found inadequate evidence to evaluate the safety or efficacy of pharmacotherapy during pregnancy.
Implementation	Successful implementation strategies for primary care practice include: • Instituting a tobacco user identification system • Promoting clinician intervention through education, resources, and feedback • Dedicating staff to provide treatment, and assessing the delivery of treatment in staff performance evaluations	
Relevant Recommendations from the USPSTF	Recommendations on other behavioral counseling topics are available at www.preventiveservices.ahrq.gov.	

For a summary of the evidence systematically reviewed in making these recommendations, the full recommendation statement, and supporting documents, please go to www.preventiveservices.ahrq.gov.

Case Studies

Coverage of Tobacco Cessation Interventions

- On May 2, 2014, the U.S. Departments of Health and Human Services, Labor and Treasury issued a Frequently Asked Questions ("FAQ") guidance document translating the USPSTF recommendation into insurance coverage policy

Q5: The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. What are plans and issuers expected to provide as preventive coverage for tobacco cessation interventions?

As stated earlier, plans may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified in the recommendation or guideline regarding that preventive service. Evidence-based clinical practice guidelines can provide useful guidance for plans and issuers.[13] The Departments will consider a group health plan or health insurance issuer to be in compliance with the requirement to cover tobacco use counseling and interventions, if, for example, the plan or issuer covers without cost-sharing:

1. Screening for tobacco use; and,
2. For those who use tobacco products, at least two tobacco cessation attempts per year. For this purpose, covering a cessation attempt includes coverage for:
   - Four tobacco cessation counseling sessions of at least 10 minutes each (including telephone counseling, group counseling and individual counseling) without prior authorization; and
   - All Food and Drug Administration (FDA)-approved tobacco cessation medications (including both prescription and over-the-counter medications) for a 90-day treatment regimen when prescribed by a health care provider without prior authorization.

This guidance is based on the Public Health Service-sponsored Clinical Practice Guideline, Treating Tobacco Use and Dependence: 2008 Update, available at: http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html#Clinic.

Case Studies

Coverage of Tobacco Cessation Interventions

- In March 2015, the American Lung Association issued a report examining state implementation of tobacco cessation coverage requirements by Qualified Health Plans ("QHPs") offered through state-based and federally-facilitated Health Insurance Exchanges
  - The American Lung Association looked at whether issuers of QHPs are providing coverage of all seven FDA-approved tobacco cessation medications as required by the ACA and the FAQ guidance
  - The report found that compliance was marginally higher in state-based exchanges than in federally-facilitated exchanges, although compliance varied by state

	Full Compliance (all 7 FDA-approved cessation meds, no cost-sharing or prior authorization indicated)	Listed all 7 cessation meds on formularies	Listed all 7 cessation meds on formularies, no cost-sharing indicated	No prior authorization required for any or all of cessation meds
Overall	17.2%	41.4%	18.1%	10.1%
Federal	-	40.1%	17.5%	-
State	-	44.8%	19.8%	-

Case Studies

Coverage of Obesity/Overweight Behavioral Counseling Interventions

	2012 Recommendation	2014 Recommendation
Recommendation	Screen all adults for obesity. Offer or refer patients with a BMI of 30 kg/m² or higher to intensive, multicomponent behavioral interventions.	Offer or refer adults who are overweight or obese and have additional CVD risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.
Grade Level	B	B
Population	18+	18+ in primary care settings who are overweight or obese and have known CVD risk factors
Required Preventive Service	• Obesity screening. • Offer or referral of intensive, multicomponent behavioral interventions for patients with BMI of 30 kg/m² or higher	• Intensive behavioral counseling for overweight or obese adults who have CVD risk factors and have been offered or referred by a clinician
Interventions	Include: • Behavioral management activities • Improving diet or nutrition and increasing physical activity • Addressing barriers to change • Self-monitoring • Strategizing how to maintain lifestyle changes Patients may be referred from primary care to community-based programs.	Include: • Changes to dietary intake and physical activity • Selected intermediate clinical outcomes (lipid levels, blood pressure, fasting glucose levels, diabetes incidence, and weight) • Didactic education • Audit and feedback • Problem-solving skills • Individualized care plans Typically delivered by specially trained health professionals.

Case Studies

Coverage of Obesity/Overweight Behavioral Counseling Interventions

- The recommendations for obesity/overweight behavioral counseling do not define a required format for the interventions, who must provide the interventions, the duration of the interventions, or the number of sessions for purposes of establishing coverage
- Further, the U.S. Departments of Health and Human Services, Labor and Treasury have not yet issued an FAQ guidance document translating these USPSTF recommendations into insurance coverage policies
- Private payers should use the language in the USPSTF recommendation, as well as "reasonable medical management techniques", to define coverage for these preventive services

Case Studies

Coverage of Obesity/Overweight Behavioral Counseling Interventions

- The 2014 USPSTF Recommendation focuses on CVD prevention and requires both (i) a screening for and identification of a patient being overweight or obese, and (ii) a screening for and identification of additional CVD risk factors prior to the counseling services being covered as a preventive service
- Intensive behavioral counseling interventions evaluated by the USPSTF **typically**:
  - Focused on behavior change (dietary intake and physical activity);
  - Included "didactic education plus other components, such as an audit and feedback, problem-solving skills, and individualized care plans";
  - Had 5-16 contacts over 9-12 months, depending on the intensity;
  - Included both in-person sessions and additional telephone contacts; and
  - Were delivered by specially trained health professionals

Case Studies

Coverage of Obesity/Overweight Behavioral Counseling Interventions

- The USPSTF contemplates that intensive behavioral counseling services could be provided outside of a primary care setting because of the intensity and expertise required. The interventions could be adapted and delivered by local community providers, in community-based settings.
- The USPSTF also notes the challenges of developing behavioral counseling recommendations that are feasible for primary care delivery or available for referral from primary care and delivered in other settings. Two examples of well-researched interventions that the USPSTF states could feasibly be adapted and delivered in the primary care setting or by local community providers include:
  - DPP (Diabetes Prevention Program)
  - The PREMIER intervention

Case Study Overview

Specific Actions Required

Tobacco Cessation Counseling and Interventions	
Coverage Required	Plan/policy years beginning on or after September 23, 2010
Required Services	Defined in DOL FAQ (including screening, counseling sessions, and medication)
Eligible Providers	Defined in Public Health Service Clinical Guidelines (such as "various primary care clinicians" and "staff", "health system-based tobacco coordinator", or "community resources")

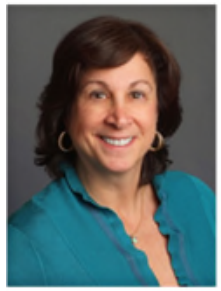
Obesity/Overweight Intensive Behavioral Counseling	
Coverage Required	Plan/policy years beginning on or after June 26, 2013 (Obesity) Plan/policy years beginning on or after August 26, 2015 (Overweight + CVD Risk)
Required Services	Flexibility to define scope of coverage, based on language in USPSTF recommendation
Eligible Providers	Flexibility to identify eligible providers, including community-based and non-traditional providers (such as DPP providers)

Conclusions

Considerations for Private Health Plans/Payers and Providers

- Private payers and providers should have an appreciation for the USPSTF and how recommendations for preventive services are implemented
  - The USPSTF may rely on the evidence considered under previous recommendations when developing new recommendations (i.e., related recommendations build on each other, such as tobacco cessation, obesity, and overweight intensive behavioral counseling)
- Private payers and providers must understand the mandatory coverage requirements related to USPSTF recommendations with an "A" or "B" rating
  - The trend is toward coverage of more preventive services rather than less
- Private payers and providers must:
  - Monitor USPSTF recommendations (including new and revised recommendations);
  - Understand how they can influence the USPSTF recommendation process; and
  - Implement coverage requirements in a compliant manner

Discussion: Q&A



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