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Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act

Comment On: IRS-2010-0040-0001

Value-Based Insurance Design in Connection with Preventive Care Benefits; Information Requests

Document: IRS-2010-0040-0005

Comment on FR Doc # 2010-32612

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See attached file(s)

Attachments**IRS-2010-0040-0005.1:** Comment on FR Doc # 2010-32612

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PART ONE: Comments Regarding Regulatory Guidance

1. What specific plan design tools do plans and issuers currently use to incentivize patient behavior, and which tools are perceived as most effective (for example, specific network design features, targeted cost-sharing mechanisms)? How is effective defined?

Oregon's approach to value-based insurance design (VBID) includes, but goes beyond the USPTF recommended preventive services. While we understand that PPACA does not specifically address VBID outside the recommended preventive services, care needs to be taken that the regulations are not written in such a way as to thwart efforts to apply value-based insurance design to other benefits, whether inside or outside the Essential Health Benefit Package. For example, benefit plans sponsored by the Oregon Health Authority have already waived cost sharing for maintenance medication for certain chronic diseases, and placed additional copays on services that have less evidence supporting their impact on health. The Oregon Health Policy Board recently decided to pursue a broader implementation of value-based insurance design based on similar principles. See <http://www.oregon.gov/OHPPR/HPB/VBEBP/index.shtml> for background information and the latest information on this process.

With regard to the USPTF preventive services Oregon has been pursuing value-based design for several years. Oregon's proposed design provides "no or low cost sharing" for value-based services, which includes most USPTF-recommended preventive services at levels A & B. However, it also includes the same level of cost sharing for certain other "value-based services" which include medications, tests or treatments that are highly effective, low cost and have ample evidence supporting their use. Conversely, services deemed "preventive" but which do not meet these criteria would be targeted for higher levels of cost sharing, as their clinical benefit to patients is smaller or uncertain.

2. Do these tools apply to all types of benefits for preventive care, or are they targeted towards specific types of conditions (for example, diabetes) or preventive services treatments (for example, colonoscopies, and scans)?

As indicated above, Oregon's objective is to move towards a benefit design that sends patients price signals which correspond to clinical value. Preventive services aren't treated any different than any other services—those with low clinical value would have high cost sharing, and those with high clinical value would have lower cost sharing, or be provided without cost sharing.

3. What considerations do plans and issuers give to what constitutes a high-value or low-value treatment setting, provider, or delivery mechanism?

Oregon has in the past discussed providing a lower level of cost sharing for services provided in a Patient Centered Primary Care Home (PCPCH) than for services provided by other in-network providers. Already, state employees who choose a medical home experience significantly lower cost sharing if they choose a plan which incentivizes use of a medical home. A shortage of primary care medical homes has slowed implementation of this design. However, Oregon has

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recently defined standards for being a PCPCH and is looking at ways to incentivize the creation of more PCPCHs through payment reform mechanisms.

What is the threshold of acceptable value?

Oregon's Patient Centered Primary Care Home Standards Advisory Committee defined six core attributes that a patient-centered primary care home should meet: **1) ACCESS TO CARE** "Be there when we need you"; **2) ACCOUNTABILITY** "Take responsibility for making sure we receive the best possible health care"; **3) COMPREHENSIVE WHOLE PERSON CARE** "Provide or help us get the health care, information, and services we need"; **4) CONTINUITY** "Be our partner over time in caring for us"; **5) COORDINATION AND INTEGRATION** "Help us navigate the health care system to get the care we need in a safe and timely way"; and **6) PERSON AND FAMILY CENTERED CARE** "Recognize that we are the most important

part of the care team - and that we are ultimately responsible for our overall health and

wellness."

What factors impact how this threshold varies between services? What data are used? How is quality measured as part of this analysis? What time frame is used for assessing value?

To determine the "value" of the patient centered home setting that would qualify for the lower cost sharing, Oregon's Advisory Committee defined three levels of primary care homes determined by their ability to meet three tiers of measures. A **Basic Primary Care Home** meets all Tier 1 measures and has "foundational" structures and processes in place. In addition, an **Intermediate Primary Care Home** meets many Tier 2 or Tier 3 measures, meets some "additional" measures, has additional structure and process improvements in place and demonstrates performance improvement. Finally, an **Advanced Primary Care Home** meets most Tier 2 and Tier 3 measures and many "additional" measures, is accountable for quality, utilization and cost of care and has mature performance improvement capacity and ability to manage populations of patients. See Appendix D of http://www.oregon.gov/OHPPR/HEALTHREFORM/PCPCH/docs/FinalReport_PCPCH_Update_d.pdf for a full listing of the measures by tier.

For the "value" of particular services, as outlined in the Authority's VBID, please see answer to #7 and the materials on the website <http://www.oregon.gov/OHPPR/HPB/VBEBP/index.shtml>

Are the data readily available from public sources, or are they internal and/or considered proprietary?

See answer to #7 for "value" of services.

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4. *What data do plans and issuers use to determine appropriate incentive models and/or amounts in steering patients towards high-value and/or away from low-value mechanisms for delivery of a given recommended preventive service?*

Oregon worked with actuaries to design how best to assign incentives, in initial design phases. Further evaluation has taken into account the defined structure of the requirements of the Exchange that will drive the overall actuarial value, and it appears that lowering cost sharing for those with most evidence for effectiveness while adjusting up those with more marginal effectiveness is doable within the confines of Bronze, Silver, Gold, etc. of the Exchange.

5. *How often do plans and issuers re-evaluate data and plan design features? What is the process for re-evaluation?*

Specifically:

- a) *How is the impact of VBID on patient utilization monitored?*
- b) *How is the impact of VBID on patient out-of-pocket costs monitored?*
- c) *How is the impact of VBID on health plan costs monitored?*
- d) *What factors are considered in evaluating effectiveness (for example, cost, quality, utilization)?*

Oregon anticipates using its All-payer, All-claims data base to look collectively at utilization, quality metrics and costs both prior to and after the Exchange gets operational at both the plan levels and statewide. Patient satisfaction surveys likely should include some questioning of benefits. Our state plan does regular surveys at time of enrollment, in addition to using other data bases (BRFFS) to assess our populations and their needs, satisfaction with design, etc.

6. *Are there particular instances in which a plan or issuer has decided not to adopt or continue a particular VBID method?*

While Oregon's Health Policy Board moved enthusiastically to support value-based design, the board has recognized implementation concerns will require a gradual approach in order to minimize confusion and adverse impact on various stakeholders. Our state employees and school district groups have started to phase in elements of a VBID, primarily around some preventive services for low to no cost-sharing, coupled with the higher cost share for preference sensitive conditions.

If so, what factors did they consider in reaching that decision?

Oregon's largest health plans initiated the gradual approach, targeting high cost procedures in order to lower costs to appeal to business, especially small businesses. Recent state-funded focus group results showed that payers, providers, employers, insurance brokers and patients all had

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concerns about clear information being available to patients and providers at the point of decision about a particular service. In addition, focus group results predicted significant administrative barriers to implementation of the value-based essential benefit package as originally envisioned and modeled by our actuary.

7. *What are the criteria for adopting VBID for new or additional preventive care benefits or treatments?*

Oregon's evaluation and prioritization is based on clinical evidence, as evaluated by a panel made up of clinicians and advocates. The Health Services Commission, which sets priorities for Oregon's Medicaid population and is the underlying methodology for the Oregon Health Authority's VBID, recently adopted the following criteria for topic review as an aid to advocates who present to the commission. This was adopted to provide a transparent explanation of how the HSC evaluates materials. We anticipate that Oregon's approach to value-based insurance design for other populations will follow a similar evidence hierarchy. This could be done on a larger collective basis, as Oregon shares in getting information for its prioritization with other states through sharing the cost and analysis of gathering information for medical technology and pharmaceuticals. The prioritization could also be done collectively and/or shared to keep costs to individual plans, states, or others down by not requiring re-creating its own methods. Conflicts of interest would need to be scrutinized to avoid bias and all processes transparent.

Guidelines for Submitted Materials to the Health Services Commission (HSC)

The HSC relies heavily on high quality evidence and evidence-based guidelines in making its prioritization decisions. Lower quality evidence may be considered in situations where higher quality evidence is difficult to obtain (e.g., rare clinical conditions). Clinical judgment will still need to be used by the Commission to determine whether the available evidence is sufficient and compelling enough to affect prioritization decisions.

The following types of evidence are considered high quality:

- Systematic reviews of randomized controlled trials
- Systematic reviews of prospective cohort studies
- Evidence-based guidelines from trusted sources

Examples of Sources of high-quality evidence

- Agency for Healthcare Research and Quality (AHRQ)
<http://www.ahrq.gov/clinic/>
- Blue Cross Blue Shield Technology Evaluation Center (TEC)
<http://www.bcbs.com/blueresources/tec/>
- British Medical Journal (BMJ) Clinical Evidence
<http://www.clinicalevidence.com>
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA)
<http://www.cadth.ca/index.php/en/hta>
- Cochrane Database of Systematic Reviews
<http://www2.cochrane.org/reviews/>
- Evidence-Based Practice Centers (EPC)
www.ahrq.gov/clinic/epc
- Health Technology Assessment Programme - United Kingdom
<http://www.hta.nhsweb.nhs.uk/ProjectData>
- National Institute for Clinical Excellence (NICE) - United Kingdom

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- <http://guidance.nice.org.uk/>
- Scottish Intercollegiate Guidelines Network (SIGN)
<http://www.sign.ac.uk/guidelines/index.html>
- University of York
<http://www.york.ac.uk/inst/crd/>

The following sources are considered medium quality and are often examined by the HSC.

- Guidelines issued by professional societies and advocacy organizations (e.g. American Heart Association)
- Coverage decisions by private health plans (e.g. Aetna)
- Well-conducted, peer-reviewed individual studies (experimental or observational)

The following types of evidence are considered low quality and are rarely reviewed by the HSC

- Case reports, case series
- Unpublished studies (posters, abstracts, presentations, non-peer reviewed articles)
- Individual studies that are poorly conducted, do not appear in peer-reviewed journals, are inferior in design or quality to other relevant literature, or duplicate information in other materials under review by the Commission
- The HSC Medical Director will include a summary of high quality evidence in the meeting packets, along with the documents themselves, for the Commissioners to review. Discretion will be used, with the HSC Medical Director consulting with the Health Outcomes Subcommittee Chair, to determine if medium or low quality sources will be included for Commissioner review. A listing of other materials submitted but not included for Commissioner review will also be included in the packets to acknowledge their receipt, along with the reason for their omission.

8. Do plans or issuers currently implement VBIDs that have different cost-sharing requirements for the same service based on population characteristics (for example, high vs. low risk populations based on evidence)?

This is difficult to achieve with large diverse populations because of limitations of medical coding (ICD-9 and procedure codes). These difficulties are discussed in more detail below. However, many plan sponsors are very aware of the population characteristics and claims experience of their employees in general, and therefore focus benefit design innovation around the needs of a particular population. For instance, one population might have a high incidence of back pain compared to other plans across the nation, and a low incidence of congestive heart failure. Therefore, this plan might find ways to structure cost sharing so as to encourage participants to use the most cost-effective, minimally-invasive treatment, preventing the costs associated with chronic back pain. Designing benefits to encourage effective (and cost-effective) treatment of congestive heart failure would provide little clinical benefit to participants or financial benefit to the plan sponsors. Another population may have little low back pain and more congestive heart failure, so the plan sponsor may choose to focus on congestive heart failure instead of low back pain.

9. What would be the data requirements and other administrative costs associated with implementing VBIDs based on population characteristics across a wide range of preventive services?

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Current medical coding systems on which most claims payment is based (ICD-9-CM/CPT/HCPCS/DRG) do not provide adequate information about the population characteristics. ICD-10-CM does not provide much additional nuance. Payers have to create other ways to get at patient characteristics such as age and health status. Most payer systems only look at the primary procedure code to determine payment and seldom link to the primary diagnosis, let alone secondary diagnoses or health status indicators. The HIPAA standardized transactions limiting what kind of information claims payment systems can require are a barrier. Even where data is available, the cost and complexity of adding clinical information to claims payment logic is a barrier to the implementation of effective value-based design.

For example, the USPTF recommendations that only adults with high blood pressure be screened for diabetes. However, when the claim for diabetes screening comes into the payer, information about the patient's blood pressure status is not available. Therefore, most claims payment systems would pay this claim as the cost of the service itself is relatively low for a single claimant (though the cost of follow-up care for a patient screened unnecessarily may not be insignificant). On the other hand, screening colonoscopies are not recommended for a 30-year old male by the USPTF. However adding logic to differentiate screening from diagnostic colonoscopies may be difficult for carriers (due to the lack of distinct CPT codes for each). Adding additional logic to limit the provisions of screening colonoscopies without cost sharing by age will create additional expense for carriers.

Data gaps in the standardized HIPAA claims transactions and/or coding sets make it difficult for payers to know the health value of a recommended preventive service for a specific patient. In the absence of proper information, it will be very difficult to efficiently implement value-based benefit design for preventive services for services whose value depends on patient characteristics.

Despite the cost and complexity of closing this data gap, doing so would allow for more effective implementation of value-based insurance design for preventive (and other) services.

10. What mechanisms and/or safety valves, if any, do plans and issuers put in place or what data are used to ensure that patients with particular co-morbidities or special circumstances, such as risk factors or the accessibility of services, receive the medically appropriate level of care?

For example, to the extent a low-cost alternative treatment is reasonable for some or the majority of patients, what happens to the minority of patients for whom a higher-cost service may be the only medically appropriate one?

Guidelines could be created based on evidence, with attention to particular population focused studies, where there is sufficient evidence. This could be applied thru a prior authorization process or other means. This is not too dissimilar to "step-therapy" many plans have done to date for pharmaceutical products, where the certain subset could proceed with a treatment at the lower cost.

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11. What other factors, such as ensuring adequate access to preventive services, are considered as part of a plan or issuer's VBID strategy?

Tying back to patient-centered primary care home access, as noted above, is a key element as is having little or no cost-sharing barriers to those selected key preventive and chronic disease maintenance services.

12. How are consumers informed about VBID features in their health coverage?

Informing consumers about benefit design is a challenge, but also key to the effectiveness of value-based insurance design. Many consumers have trouble understanding a standard insurance design, and a value-based design can add more complexity.

Value-based insurance design is a mechanism to send price signals to patients about the clinical value of the health care they choose (and choose not to receive). In the U.S. marketplace, price signals regarding health care services are muddled because of the fragmented nature of the marketplace. Already, patients often do not know the price of a procedure when they make decisions; a comprehensive value-based design increases the complexity of a benefit plan. Transparency and education of all parties involved in a value-based design is essential, to ease administration and increase satisfaction, but also to ensure that the price signals have the intended effect on treatment decisions to the maximum extent possible. Typical education programs include mailings (sometimes targeted to patients with certain conditions) and workplace seminars. However additional, education and explanation will often be necessary as patients make treatment decisions while they are faced with conditions that they are seeking treatment for.

Several plans in Oregon have worked together to develop a "tool kit" of how to talk with plan members about VBID based on national and local expertise. The Oregon Health Authority is working through its Public Purchasers Committee of its' Policy Board to expand the communication tools and broaden awareness to other public and private purchasers to assist them in making a decision to offer VBID to their employees and be successful at helping their employees understand and appreciate their benefits.

13. How are prescribing physicians/other network providers informed of VBID features and/or encouraged to steer patients to value based services and settings?

Payers with significant market share with a package of identical benefits have the leverage to inform and educate providers. For plans that make up a small portion of any given provider's patient population, it does little good to educate providers. PPACA's essential health benefit package and the USPTF-defined services will provide some standardization, in the sense that there will be a uniform set of services to be provided by all private payers (except grandfathered plans). The regulations will need to balance the need for standardization (to ease communication) with the need to allow flexibility so that it allows for reasonable medical management so that services of low (or negative) health value to the patient are not inappropriately incentivized.

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The Oregon Health Authority is starting to develop how best to align payment reforms with the value-based benefit changes. As one is asking the person to pay more in order to carefully weigh a particular service's benefit to their health, the providers need to be incentivized to also direct the person to those with more efficacy, which would need to be done in restructuring payments and paying less to a provider for those marginally effective procedures, more for the more effective procedure. This will align the prescribing provider with the patient, rather than against each other, or confuse the patient how to reconcile his/her benefit design with their providers' advice.

14. What consumer protections, if any, need to be in place to ensure adequate access to preventive care without cost sharing, as required under PHS Act section 2713?

Making plans be accountable back to employers/purchasers is critical for many aspects of cost, quality and utilization to ensure adequate safeguards against what doomed managed care of the 80's, which included underutilization of services. Clear, accountable expectations that are uniform, not too onerous to comply with and reporting back on outcomes, not just processes are critical. It will require the plans to use data in a new way, or require states and the federal government to use collective data, such as All Payer, All Claims databases to ensure appropriate utilization based on sound modeling that is open and transparent, not individual proprietary analyses.

PART TWO Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act

The Paperwork Reduction Act (PRA) requires an estimate of how many respondents will be required to comply with any "collection of information" requirements contained in regulations and how much time and cost will be incurred as a result. A collection of information includes recordkeeping, reporting to governmental agencies, and third-party disclosures.

The Departments are requesting comments that may contribute to the analyses that will be performed under these requirements, both generally and with respect to the following specific areas:

1. What costs and benefits are associated with expanded use of VBID methods?

How do costs and benefits vary among different types of preventive screenings, lifestyle interventions, medications, immunizations, and diagnostic tests?

See the Oregon Health Services Commission work on developing its value based services that should be offered without barriers. Links at <http://www.oregon.gov/OHPPR/HPB/VBEBP/index.shtml> for background information and the latest information on this process.

2. What policies, procedures, practices and disclosures of group health plans and health insurance issuers would be impacted by expanded use of VBID methods?

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What direct or indirect costs and benefits would result? Which stakeholders will be impacted by such benefits and costs?

Oregon has some plans with experience with, including our Oregon Educators Benefit Board's plans and one of the plan's own employee group. Further information could be provided upon request.

3. What impact would expanded use of VBID methods have on small employers or small plans?

Are there unique costs or benefits for small plans? What special considerations, if any, should the Departments take into account for small employers or small plans?

Oregon's Purchasers' Coalition and others have been furthering through collaborative efforts information and resources to assist smaller businesses. The return on investment is to bend the cost curve and maintain affordability of these employers continuing to be able to offer coverage and is critical to the success of Federal reform and the Exchanges. Efforts such as eValue8 and other efforts to do things together and share resources is important for affordability of using VBID and put value towards prevention and maintenance of chronic disease.