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February 28, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: HHS-OS-2010-002, Request for Information Regarding Value-Based Insurance Design in Connection With Preventive Care Benefits

Dear Secretary Sebelius:

U-Systems, Inc. is pleased to offer comments regarding the potential application of value-based insurance design (VBID) to the coverage of recommended preventive services, consistent with Section 2713 of the Affordable Care Act (ACA). Our comments reflect the unique perspectives of an innovative medical device company whose mission, for the last 14 years, has been to design and develop an ultrasound imaging product to assist radiologists in addressing an unmet need for the early detection of breast lesions in women with dense breast tissue.

RFI Questions

As a medical device company, we are not in the position of providing information to most of the questions listed in the RFI. However, questions 7 and 10 raise important issues that are very relevant to our particular concerns about encouraging investments in innovations that address unmet needs and ensuring that all women have access to the most appropriate breast cancer screening tests and are not limited to conventional X-ray mammography, known to be inadequate for some women. The issues raised by these two questions have framed our recommendations as to when VBID could be used to encourage innovations that address unmet needs and when VBID should not be used because it would be unfair to specific sub-populations with particular characteristics.

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

With regard to this question, we would hope that the VBID guidelines would encourage VBID's potential application for FDA-approved innovations which –

- have been developed to improve health outcomes for population sub-groups not adequately served by current tests or preventive services,
- have not yet been included in one of the recommendations or guidelines referenced in Section 2713 of the ACA, and
- are in the early stage of adoption by healthcare providers.



The first criteria is similar to those used by the FDA to determine if a device qualifies for expedited review. Specifically, based on criteria from the *Least Burdensome Approach*, special review is afforded to devices that meet one of the following criteria:

- 1) the device represents a breakthrough technology;
- 2) there are no approved alternatives;
- 3) the use of the device offers significant advantages over existing approved alternatives;
- 4) availability is in the best interest of the patients.¹

With regard to breast cancer screening, multiple studies have demonstrated that conventional X-ray mammography, while still the gold standard for breast cancer screening, is not enough for women with dense breast tissue. For example, a recent publication in the *New England Journal of Medicine* by Norman Boyd concludes; "*As compared with women with density in less than 10% of the mammogram, women with density in 75% or more had an increased risk of breast cancer (odds ratio, 4.7; 95% confidence interval [CI], 3.0 to 7.4), whether detected by screening (odds ratio, 3.5; 95% CI, 2.0 to 6.2) or less than 12 months after a negative screening examination (odds ratio, 17.8; 95% CI, 4.8 to 65.9).* Increased risk of breast cancer, whether detected by screening or other means, persisted for at least 8 years after study entry and was greater in younger than in older women. For women younger than the median age of 56 years, 26% of all breast cancers and 50% of cancers detected less than 12 months after a negative screening test were attributable to density in 50% or more of the mammogram."²

By allowing health plans to apply VBID to FDA-approved devices that meet criteria, such as the three criteria listed above, health plans may be more willing to cover and apply lower co-payments for new adjuncts to mammography for this sub-group of women, before they are included in federal guidelines.

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 comorbidities or special circumstances, such as risk factors or the accessibility of services, receive the medically appropriate level of care?

The commentary that follows this question in the RFI reflects one of the most important issues at the core of breast cancer screening --- how to develop an equitable approach when different population sub-groups, such as women with dense breast tissue, have a need for different screening tests. While conventional X-ray mammography may be low-cost and reasonable screening test for the majority of women, by itself, it may not provide adequate information for women with dense breast tissue, a factor that the American Cancer Society (ACS) has assigned to the moderate risk category. Although current adjunctive technologies such as hand-held ultrasound can detect cancers in women with dense breast tissue following a "normal" mammogram (asymptomatic patients), this is not the primary use of breast ultrasound today.

¹ Section 202, FDA Modernization Act of 1997: Special Review for Certain Devices

² *Mammographic Density and the Risk and Detection of Breast Cancer*. [Norman F. Boyd, M.D., D.Sc., Helen Guo, M.Sc., Lisa J. Martin, Ph.D., et.al. *Engl J Med* 2007;356:227-36.]



Hand-held ultrasonography is too resource intensive, particularly where a specific area of interest is not known and the whole breast has to be scanned by hand. The more common use is directed at symptomatic patients, who have a suspicious mass on mammography or a palpable lump.

As a result of current limitations, the population of asymptomatic women with dense breast tissue is at higher risk of having undetected cancers. In many cases today, cancers in these patients will not be found until they are palpable, a pattern known to result in poorer outcomes and higher cost of treatment.

As noted above, absent the timely inclusion of innovative adjunctive technologies in the USPSTF recommendations for breast cancer screening, VBID could expand access to innovations related to an important unmet need. However, once the adjunct tests are included in a recommendation (with an A or B rating), VBID's application could raise important equity issues, particularly if it is used as a means of applying co-payments for the adjunctive tests, even if the co-payment is not applied to the conventional X-ray mammography service.

Below, we provide some additional background information about our company and our understanding of how VBID could be applied to preventive services, consistent with Section 2713, and when it would be inappropriate to apply VBID.

U-Systems: Investing in Innovations Related to Unmet Needs

The company's history, investments and product focus reflects our commitment to addressing the unmet screening needs of women with dense breast tissue for whom mammography alone does not provide enough information. The company has incorporated proprietary hardware and software technology into a unique system, the *somo•v*TM Automated Breast Ultrasound. The *somo•v* received a 510(k) clearance from the Food and Drug Administration (FDA) for adjunctive diagnostic use with mammography. For the last several years, the company has made significant investments developing the scientific and statistical foundation for its use as an adjunctive screening test with mammography. The recent completion of a pivotal ROC Reader Study for automated breast ultrasound cancer screening will be a foundational element of a Pre-Market Application (PMA) that the company plans to file with the FDA regarding the use of *somo•v* ABUS as an adjunct to screening mammography for women with dense breast tissue.

The reader study was conducted by University of Chicago, an acclaimed pioneer in women's health research, with Maryellen Giger, Ph.D., Professor of Radiology at the University of Chicago serving as the principal investigator. The multi-reader, multi-case (MRMC) ROC Reader Study was carried-out to evaluate the sensitivity of *somo•v*TM Automated Breast Ultrasound (ABUS) together with a screening mammogram in detecting breast cancer in women with dense breast tissue.

As noted by Dr. Giger, *"For most women, mammography remains the gold standard for the early detection of breast cancer, but multiple studies have demonstrated that it is not enough for women with dense breast tissue The primary objective of this reader study was to determine the impact of ABUS on Reader (interpreting physician) performance when used in combination*



with mammography as a screening modality for asymptomatic women with dense breast tissue. This study brings us one step closer to earlier detection of breast cancer using ultrasound as an adjunctive screening tool.”

VBID for Preventive Services

As noted in the RFI published in the **Federal Register**, VBID includes the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments, and services. The reduction or elimination of cost-sharing for “high value” services, such as maintenance drugs used for chronic conditions or screening services, is the most commonly applied VBID incentive. In some of the more advanced VBID programs, these cost-sharing changes are applied only when the high value service is delivered by a healthcare provider designated as a “high performer”.

Health plan members view the lower cost-sharing of VBID as a more generous approach to coverage.³ In contrast, the use of VBID within the context of preventive services is more likely to be perceived as a reduction in benefits because of the ACA’s requirement that health plans cover preventive services without any cost-sharing requirements. Although the interim final rule implementing the preventive services provision did not address VBID directly, its application can be seen in the special status afforded to “in-network” providers, presumably used as a proxy for defining a high performing provider.⁴ Specifically, the regulation gives health plans the flexibility to limit coverage and to require cost-sharing if the preventive service is not delivered by a provider within the health plan’s network.

Section 2713: Coverage Of Preventive Health Services

The coverage of preventive health services is addressed in three sub-sections of Section 2713 of the ACA.

- § 2713(a) references those preventive services that should be covered without any cost-sharing requirements.
- § 2713(b) describes the intervals associated with the preventive services.
- § 2713(c) authorizes the use of VBID in the coverage of preventive services.

Importantly, § 2713(a) concludes with the following statement: *“Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force”*. As such, it would be reasonable to conclude that, subject to the VBID guidelines related to § 2713(c), health plans could –

³ *Value-based Insurance Design: Aligning Incentives to Bridge the Divide Between Quality Improvement and Cost Containment*, A. Mark Fendrick, MD; and Michael E. Chernew, PhD, *The American Journal Of Managed Care* December 2006.

⁴ *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*, **Federal Register**, Vol. 75, No. 137, July 19, 2010.



- cover preventive services beyond those recommended by the US Preventive Services Task Force (USPSTF), and
- apply VBID elements, such as a reduced co-payments, to these services when they are obtained from a “high performing” provider.

However, once a service has been included as a guideline or recommendation of the three organizations listed in § 2713(a), it would be inappropriate to allow cost-sharing to be applied when they are obtained from an in-network provider.

Recommended Use of VBID in Preventive Services

Although there may be many appropriate ways to apply VBID to preventive services, we believe that it could have an important role in expanding health plan coverage of innovative preventive services, prior to their inclusion in the list of guidelines and recommendations outlined in Section 2713.

Consistent with the language at the end of § 2713(a), we urge the Departments to include, in the VBID guidelines, an acknowledgement that health plans could apply VBID to preventive services other than those specifically enumerated in § 2713(a), if they meet certain requirements. For example, if the service requires a product that requires regulatory approval by the FDA, the preventive service could be covered at a lower co-payment if it had the necessary regulatory approval and if the health plan complied with the fundamental approach of VBID by providing information and incentives for consumers that promote access.

In the context of breast cancer screening, FDA-approved innovations such as adjuncts to screening X-ray mammography, for women with dense breast tissue, could be covered under VBID, prior to their evaluation by the USPSTF, if,

- women receive relevant information, such as their breast density score and how that information impacts the adequacy of relying on conventional mammography results alone,
- the test is performed by a provider that meets performance criteria established by the health plan.

Providers could use a shared decision-aid for breast cancer screening to provide women with the relevant information, particularly their breast density score and its relevance to understanding various test results.

We have framed our suggestion about the use of VBID to enhance access to tests that fill an unmet need in the context of breast cancer screening because of the familiarity with the issues that we have developed over the last 14 years as we have developed *somo•v™*. However, the suggestion could easily apply to other new and innovative preventive services related to other unmet needs.



Conclusion

In contrast to the general perception that VBID is a benefit enhancement because a health plan member can access valuable services with lower co-payments, VBID's application to preventive services could become a benefit restriction unless the federal guidelines for VBID achieve the right balance between encouraging innovation to address unmet health needs and ensuring an equitable approach to providing access to the right screening tests based on an individual's risk factors.

- **Innovations and Unmet Needs:** The federal VBID guidelines should allow, if not encourage, health plans to apply VBID features to coverage of preventive services that respond to an unmet need, prior to their inclusion in federal guidelines or recommendations.
- **Risk Factors and Equity:** The federal VBID guidelines should not allow inequities among sub-populations with risk factors. In particular, cost-sharing should not be applied to unique testing needs such as an adjunctive screening test, once it has been included in a federal guideline or recommendation if they are obtained from an in-network provider.

Thank you for the chance to provide U-System's view on this important policy development.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ron Ho', with a stylized flourish at the end.

Ron Ho
President & Chief Executive Officer