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***SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV***

Marilyn Tavenner, RN  
Acting Administrator and Chief Operating Officer  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue S.W.  
Washington, DC 20201

Farzad Mostashari, MD  
National Coordinator for Health Information Technology  
Patriots Plaza III  
355 E Street, SW  
Washington, DC 20201

Re: Request for Information on Advancing Interoperability and Health Information Exchange  
[CMS-0038-NC]

Dear Administrator Tavenner and Dr. Mostashari:

On behalf of the Society for Participatory Medicine, we are writing to provide some specific suggestions in response to the above-referenced RFI. We hope that you accept these recommendations so that interoperability and health information exchange may advance to the point that our true underlying goal, improved patient-centered care, may be achieved.

The Society for Participatory Medicine has individual and institutional members nationwide comprising patients, non-professional caregivers, and clinicians. It was founded to study and promote participatory medicine, which is centered around networked patients shifting from being mere passengers to

responsible drivers of their health, and providers who encourage and value them as full partners. For further background on the Society and its tenets, please see the Society's website (<http://participatorymedicine.org>), its online journal, The Journal of Participatory Medicine (<http://jopm.org>) and its blog, e-patients.net (<http://e-patients.net>).

Our specific comments, keyed to the questions presented in the RFI, are as follows:

***3. To what extent do current CMS payment policies encourage or impede electronic information exchange across health care provider organizations, particularly those that may be market competitors? Furthermore, what CMS and ONC programs and policies would specifically address the cultural and economic disincentives for HIE that result in "data lock-in" or restricting consumer and provider choice in services and providers? Are there specific ways in which providers and vendors could be encouraged to send, receive, and integrate health information from other treating providers outside of their practice or system?***

CMS and ONC programs currently tend to encourage institutional control over information rather than physician and patient control and this data lock-in contributes to the potential for excessive costs and unwarranted care. Physicians are encouraged to keep referrals in-network, which may not necessarily be the lowest cost or most appropriate lab, imaging center or specialist because of the network-level control of information flow. We would prefer to see information – and choice – in the hands of patients, counseled by their health care providers.

The most effective ways to encourage HIE by providers and vendors is to put the power to connect to external services to the physicians and patients themselves. Specifically,

- All information exchanged in and out of the institution should also be available on the Blue Button Plus portal. If the information is not accessible via the BB+ interface then it should not be available for exchange through any other means. BB+ is a primary antidote to data lock-in by the institution and the vendor.
- Patients should have the right to present a self-signed certificate for access to the BB+ interfaces, Patients should also be able to provide information to be imported to the record, so long as the provenance of the information may be recorded, just as it is when it is pulled into a record from another provider.

Physicians should have the right to prescribe any health IT app or service without institutional and vendor restrictions. Referral to external apps and services should not be restricted by institutional "trust" or reciprocity agreements any more than these were restricted in the days of paper. Physician use of health IT including decision support services and disease management apps can

be regulated by professional licensure or institutional policy but should not be restricted by EHR technology or vendor practice.

**4. What CMS and ONC policies and programs would most impact post acute, long term care providers (institutional and HCBS) and behavioral health providers' (for example, mental health and substance use disorders) exchange of health information, including electronic HIE, with other treating providers? How should these programs and policies be developed and/or implemented to maximize the impact on care coordination and quality improvement?**

Blue Button Plus is the most important vehicle for empowering post-acute, long-term, behavioral health and home care providers. The use of Direct message interfaces mandated for Stage 2 EHRs should be strengthened so that external, state HIE and patient-centered health IT systems and web services can be guaranteed access to all patient information in an EHR under the sole authority of the patient.

All CMS and ONC policy that introduces delays in patient-directed access relative to institutional access should be eliminated. Patient-authorized exchange represented by Blue Button Plus queries for information will level the playing field for state HIEs and innovative web services by allowing for exchange of health information among all providers.

**5. How could CMS and states use existing authorities to better support electronic and interoperable HIE among Medicare and Medicaid providers, including post acute, long-term care, and behavioral health providers?**

CMS and states can use their purchasing authority to specify Blue Button Plus interfaces. Unlike institutional interfaces that operate under the HIPAA treatment, payment and operations (TPO) exclusion, BB+ interfaces support both HIPAA TPO and patient-directed exchange. By encouraging the use of patient-directed exchange, CMS and states can expand access to health information for non-TPO uses such as medical research, facilitate second opinions in situations where the patient is reluctant to ask for records and generally increase the transparency of quality and cost in healthcare.

**6. How can CMS leverage regulatory requirements for acceptable quality in the operation of health care entities, such as conditions of participation for hospitals or requirements for SNFs, NFs, and home health to support and accelerate electronic, interoperable health information exchange? How could requirements for acceptable quality that involve health information exchange be phased in overtime? How might compliance with any such regulatory requirements be best assessed and enforced, especially since specialized HIT knowledge may be required to make such assessments?**

CMS currently has a survey and certification program in place under which it reviews organizational and operational compliance of all provider types with Conditions of Participation, through complaint

investigation surveys and periodic unannounced recertification surveys. We propose that the surveyor manuals for each provider type be reviewed and revised so that each instructions for each "tag" that may be affected by a failure of interoperability or health information exchange explicitly direct surveyors to cite providers for such failure, and thereby require providers to file and implement plans of correction that directly address health IT interoperability and/or health information exchange issues that are among the root causes of the deficiencies cited.

***7. How could the EHR Incentives Program advance provider directories that would support exchange of health information between Eligible Professionals participating in the program. For example, could the attestation process capture provider identifiers that could be accessed to enable exchange among participating EPs?***

Provider identity should be separated from institutional affiliation and role to facilitate patient-centered and patient-directed health information exchange. The attestation process could be used to capture provider identifiers if this is done in a way that does not lock the provider into a particular institution. For example, providers should have the option to use identifiers associated with their state license or personally-controlled domain.

The attestation process could link the attesting provider with its National Plan and Provider Enumeration System record, and a Direct address field should be added to the NPPES record (rather than simply using the Direct address to attest). This would automatically place Direct addresses into the NPPES as attestation takes place, thus creating a usable and accessible directory that may be used to enable exchange among participating EPs.

***9. What CMS and ONC policies and programs would most impact patient access and use of their electronic health information in the management of their care and health? How should CMS and ONC develop, refine and/or implement policies and program to maximize beneficiary access to their health information and engagement in their care?***

Blue Button Plus with undelayed access to all of a patient's information, including notes, will create a market for decision support and other services that serve and support patients to increase competition and reduce unwarranted care. The delegation capabilities of BB+ will create a competitive market for patient services.

The BB+ program should be expanded to support all aspects of health information exchange including the operation by state HIEs of centralized consent-management and record locator services that provide the patient with a convenient single point of contact for authorization of health records sharing and accounting for disclosures across all of the various health services providers they use. This centralized

Consent and RLS service should allow the patient to use one or more voluntary identifiers such as a Direct email address.

Effective delegation of access to third-party services through BB+ that is unrestricted by institutional or vendor restrictions will engage the patient as independent third-party services compete for the opportunity to advocate and serve the patient.

At present, reportedly only ten percent of patients access their own data through a PHR. There are likely usability issues that are holding this figure down to such a low level.

The agencies must bolster patient education efforts, as well as provider and vendor usability efforts, in order to increase this percentage swiftly.

***10. What specific HHS policy changes would significantly increase standards based electronic exchange of laboratory results?***

Standards based electronic exchange of laboratory results should be unified with all other aspects of health information exchange including Direct project and Blue Button Plus without any delays and using the same non-coercive and voluntary patient ID infrastructure that will serve other aspects of exchange authorization, health records discovery and accounting for disclosures. Patients should have a right to immediate notification of results availability and the right to order and access lab results on their own.

Currently, laboratories covered under CLIA do not receive incentives for using standards specified under meaningful use. One of the requirements of clinical laboratories under CLIA is the production of a test report that meets requirements under 42 CFR 493, subsection 1291.

One possible way to promote use of the standards would be to providing a deeming clause in subsection 1291 such that if transmission of test results is performed with Health Information technology that has been certified to conform to the criteria in 45 CFR 170, subsection 314(b)(6) [ . . . ] could be an incentive for laboratories to use those standards.

While this would be a regulatory change, it could be accomplished through adding this clause in the course of finalizing the amendments to HIPAA and CLIA regulations (CMS-2319-P) proposed in 2011 , eliminating the laboratory test results exclusion from health information that must be released to patients upon request, so that such results would not have to be carved out of a record otherwise released to a patient.

We look forward to seeing accelerated interoperability of health information exchange through enhanced sub-regulatory policy changes at ONC and CMS. These changes will continue to enable the further transformation of the health care system to a patient-centered, collaborative system of care.

Please do not hesitate to contact us should you or your staff wish to discuss these recommendations further.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "skrug".

Sarah Krug  
President  
sarahkrug@cancer101.org

A handwritten signature in black ink, appearing to read "D Harlow".

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