1. Is an electronic file size an appropriate proxy for "pages" in setting fees for electronic access, or is it simply a substitute for a per-page proxy? If file size is appropriate, how should cost be calculated, particularly considering the questions below? If not, what is a better proxy for calculating labor costs for electronic access?

Cerner Reply: No, electronic file size is not an appropriate proxy, as it can vary dramatically by the type of content, independently of the complexity of the content or the labor cost to produce the content especially if it involves multiple electronic sources that need to be compiled. Equally "complex" documents could have widely varying file sizes. For example, the inclusion of a single note that includes a simple image (e.g., a photograph of a patient's lesion) could dramatically increase the overall file size. We suggest that "virtual pages" may be a better way to approximate the labor costs related to producing clinical documents which might capture measures that approximate media costs if the electronic copy is to be provided by use of portable removable media. A "virtual page" would correspond roughly to whatever mechanism is used to break up a document into readable chunks.

However, the whole notion of "pages" may become outdated, as electronic forms of data export move away from exporting documents and instead export discrete data elements, such as FHIR "bundles." The desire to get discrete and normalized data (mapped to MU data standards) will grow over time.

In a typical EHR, the effort associated with producing an export is more likely to correlate to the effort required to determine and capture the parameters for the export, identify source systems for the information that has been requested and to deal with any manner of compilation that is required prior to producing the electronic copy of the information. This work might include preparation of the information into a consolidated format that is patient/consumer usable, making determination about potentially restricting information that the provider believes would result in harm to the individual if released, and ensuring that there are no restrictions on the information's release that requires additional permission or prior provider consultation. This "set up" time is likely to be a better indicator of the overall "cost" than page counts or file sizes. (Note that if the patient is self-authorizing release of their own data, some of these set up steps might be reduced in scope.)

2. One of the objectives of Stage 2 of the Meaningful Use EHR Incentive Program is to provide individuals the ability to view, download and transmit their health information. Therefore, should the producible form and format of the electronic copy the individual requests affect how the individual is charged? (For example, an individual downloads an electronic copy onto a portable thumb drive or CD vs. using the download or transmit capabilities of certified EHR technology or email.) This issue may also arise when an individual uses personal health records or mobile health devices.

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<sup>&</sup>lt;sup>1</sup> 45 C.F.R. § 170.314.

Cerner reply: The download functionality is the same, regardless of how the patient invokes the download, or where he puts the data. That does not seem to be a good differentiator for cost. The work required to enable the patient's portal account, and to verify that identity of the patient is likely to be the dominating effort, not the means of the download itself. A differentiator of cost may be applicable if the patient rejects the use of an online capability and prefers one that makes use of removable media that has to be created by hospital staff. That may be true particularly if the patient insists on use of media they provide to the payer for use in lieu of using any provider supplied online access such that there are real labor costs to producing the electronic copy.

- 3. If, due to interoperability issues between an EHR where the requested information is maintained, and the software used to create the copy for the individual (for example, proprietary software of a business associate which provides the electronic copy to the individual), the business associate must download the file from the EHR, and subsequently upload it to the business associate's software before generating an electronic copy for an individual, should labor costs associated with this process be charged to the individual? Why or why not? If so, how should they be calculated? Additionally, if the information is located in several different EHRs,
  - downloaded, and uploaded to a separate software or system, should labor costs associated with this process be charged, as well and if so, how should they be calculated?

Cerner reply: This seems like a business decision that has little to do with EHR software. If the business associate is adding value to the data export (for example, improved formatting, compilation of discrete data into flowsheets or graphical representations) then perhaps the addition of extra charges for the value-add features would make sense. However, we feel that a standards-based data or document export should be provided to the patient at the lowest possible cost, allowing the patient to bypass any unwanted or unnecessary value-add functions provided by the business associate.

4. Similarly, if information from an EHR has to be printed on paper (therefore paginated) and then scanned and uploaded to a different software program used to create and/or send the copy for/to the individual, should the individual be charged, and if so, how should the cost be calculated?

Cerner Reply: We don't have direct experience in managing systems that take this approach but if there are preparatory steps to compile the patient's record into electronic form on account of the provider having paper based records or multiple electronic systems that are not integrated or interfaced, there is labor cost involved in the record's compilation. Whether that is fair to charge to the patient because the provider has a given state of existing recordkeeping systems is debatable.

5. Would you answer anything differently if the copy of the data from the designated record set were being transmitted to a non-HIPAA covered business, such as a PHR vendor compared to another HIPAA covered entity or that organization's business associate?

Organization: Cerner

Cerner reply: No, as long as the transfer is requested (and authorized) by the patient, the target for the data should not impact the charges.

Ideally, there would be no charge for any of these mechanisms that can leverage electronic records (EHR) to get the data to the patient. We also believe that the patient should be able to ask for automatic copying of future encounters, such as by registering a Direct Address for the target of the data. Once the consumer has registered a target system, at the end of each future encounter a message containing the encounter summary (as a CCDA) would automatically be sent to the designated recipient.