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MEMORANDUM

July 20, 2016

To: Tribal Health Clients

From: Hobbs, Straus, Dean & Walker LLP

Re: ***CMS issues final rule expanding uses of Medicare data by qualified entities***

On Thursday, July 7, 2016, the Centers for Medicare & Medicaid Services (CMS) released a final rule to implement Section 105 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to expand the purposes for which qualified entities may use and disclose data under the qualified entity program. 81 Fed. Reg. 44,456 (July 7, 2016). Under the Medicare qualified entity program, established under the Affordable Care Act, CMS makes extracts of Medicare Parts A, B, and D claims data available to "qualified entities" for purposes of evaluation and reporting on the performance of health care providers and suppliers. The qualified entity must pay a fee equal to the cost of making the data available; must combine Medicare data with claims data from other sources for reporting purposes; and must share the data they receive from CMS with providers and suppliers upon their request.[1] "Qualified entities" are described in the statute as public or private entities that are "qualified (as determined by the Secretary) to use claims data to evaluate the performance of providers of services and suppliers on measures of qualify, efficiency, effectiveness, and resource use," and that agree to meet program requirements.[2]

Under the qualified entity program as originally enacted, use of the data by qualified entities was limited to evaluation of the performance of health care providers and suppliers. Section 105 of the MACRA expands the allowable use of the data to permit qualified entities to: (1) conduct non-public analyses and provide or sell those analyses to "authorized users" for non-public use in accordance with program requirements and applicable laws, including the Health Insurance Portability and Accountability Act (HIPAA), and (2) provide or sell the combined data (or provide the Medicare-only data, at no cost) to providers, suppliers, hospital associations, and medical societies, again in accordance with program requirements and applicable laws.[3] Qualified entities that choose to utilize these new provisions must meet annual reporting

[1] Among other things, the qualified entity must also confidentially share its reports with any provider or supplier identified in the reports and give the provider or supplier an opportunity to appeal and correct errors prior to public release. 42 U.S.C. § 1395kk(e).

[2] 42 U.S.C. § 1395kk(e)(2).

[3] 42 U.S.C. § 1395kk-2.

requirements and are subject to an assessment if they or the authorized users to whom they disclose patient-identifiable data violate the terms of their Qualified Entity Data Use Agreement.

> The MACRA defines "authorized user" as:
>
> (i) A provider of services.
> (ii) A supplier.
> (iii) An employer (as defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974).
> (iv) A health insurance issuer (as defined in section 2791 of the Public Health Service Act).
> (v) A medical society or hospital association.
> (vi) Any entity not described in clauses (i) through (v) that is approved by the Secretary (other than an employer or health insurance issuer not described in clauses (iii) and (iv), respectively, as determined by the Secretary).[4]

In the final rule, utilizing the Secretary's authority to approve additional entities as authorized users, CMS includes state entities and federal agencies in the definition of "authorized user."[5] In the preamble to the final rule, CMS specifies that "federal agencies" includes the Indian Health Service and Indian Health programs. CMS explained:

> Similar to state agencies, we believe that federal agencies, particularly those that provide healthcare services such as the Indian Health Service and the U.S. Department of Veteran Affairs are important partners with CMS in transforming the healthcare delivery system and could substantially benefit from access to analyses to help improve quality and reduce costs, especially for individuals who utilize their services.[6]

The CMS final rule further amends existing program regulations to implement the expanded data use permissions; various patient privacy and data security requirements, including the requirement that a qualified entity enter into a data use agreement with CMS and with any authorized user to which the qualified entity sells or discloses combined or Medicare data; limitations on the ability of a qualified entity to utilize data for the expanded purposes, including limitations on the use and sale or disclosure of patient-identifying data; limitations on an authorized user's use of analyses and derivative data obtained from a qualified entity; requirements for a qualified entity to confidentially

[4] 42 U.S.C. § 1395kk-2(a)(9)(A).

[5] 42 C.F.R. § 401.703(j).

[6] 81 Fed. Reg. 44466.

notify a provider or supplier that is identified in a non-public analysis and to allow the provider or supplier to review and correct errors in the analysis before it is released to an authorized user; and provisions for monitoring and sanctioning qualified entities, among others. In a press release regarding the final rule, CMS stated that future rulemaking "is anticipated to expand the data available to qualified entities to include standardized extracts of Medicaid data."[7]

If you would like further information regarding this final rule, please do not hesitate to contact Elliott Milhollin at (202) 822-8282 or emilhollin@hobbsstraus.com; Geoff Strommer at (503) 242-1745 or gstrommer@hobbsstraus.com; or Caroline Mayhew at (202) 822-8282 or cmayhew@hobbsstraus.com.

[7] The CMS press release is available online at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-07-01.html.