

Statement of Commissioner Melissa Holyoak,

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a policy statement interpreting the then-current Rule in 2021 (“2021 Policy Statement”),<sup>8</sup> issued a Notice of Proposed Rulemaking on June 9, 2023 (“NPRM”), and today issues the Final Rule.<sup>10</sup>

I am encouraged that today the Commission is acting by rulemaking, as authorized by statute and following a period of notice and comment that elicited a range of views, rather than acting by fiat in a policy statement, as the Commission did in 2021. I cannot endorse any policy statement that either displaces Congress’s authority to make law or subverts the rulemaking process. The 2021 Policy Statement did both. The majority clearly recognizes this overreach. After all, if the 2021 Policy Statement had any force, today’s rulemaking would be unnecessary.

Setting aside its troubling history, I turn to the Final Rule itself, which, unfortunately, I find equally troubling in its extension beyond the parameters established by Congress.

Some background first. Under the Recovery Act, PHR identifiable health information means “individually identifiable health information,” as defined by the Social Security Act, 42 U.S.C. § 1320d(6).<sup>12</sup> The Social Security Act defines “individually identifiable health information” as information that is “created or received by a health care provider, health plan, employer, or health care clearinghouse.”<sup>13</sup> The Social Security Act then defines “health care provider” to include three categories: [1] a provider of services (as defined in 1395x(u) of this title), [2] a provider of medical or other health services (as defined in section 1395x(s) of this title), and [3] any other person furnishing health care services or supplies.<sup>14</sup>

The Commission takes liberties with the final category in that definition (“any other person furnishing health care services or supplies”) to adopt a new, capacious definition of “covered health care provider” and a new, similarly capacious definition of “health care services and supplies,” whose joint effect is to sweep a large swath of apps and app developers under the purview of the Final Rule. These expansive definitions are not consistent with the statute. Under longstanding principles of statutory interpretation, the final category of provider (“any other person...”) must be understood in relation to the first two categories (“provider of services” and “provider of medical or other health services”).<sup>15</sup>

that list presumptively has a similar meaning under the canon of noscitur a sociis.<sup>16</sup> And when a general term follows a list of specific terms, the general term “should usually be read in light of those specific words to mean something similar.”<sup>17</sup> Together, these canons instruct that the final category of health care providers that includes the general term “other person” must be similar to the more specific terms that precede it.

The first two categories of health care providers incorporate the definitions of Sections 1395x(u) and 1395x(s) of the Social Security Act, respectively.<sup>18</sup> The first category of provider includes “a hospital, critical access hospital, rural emergency hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program fund.”<sup>19</sup> The second category of provider includes an extensive list (Section 1395x) includes 17 paragraphs and over 35 subparagraphs of medical professionals including physicians, physician assistants, nurse practitioners, clinical psychologists, clinical social workers, and others, and the specific services administered by medical professionals.<sup>20</sup> These two categories comprise traditional forms of health care providers.

The final category, addressing “any other person furnishing health care services or supplies” must therefore only include persons that are “similar in nature to the first two categories.”<sup>21</sup> The majority argues that my “effort to cabin the third category reads it out of existence, violating the canon that holds interpretations giving effect to every clause of a statute are superior to those that render distinct clauses superfluous.”<sup>22</sup> This application of the canon is incorrect. Requiring similarity among categories does not result in superfluity; it merely prevents interpretations that extend beyond what the text permits. As a result, the majority’s limited application due to its context is not a reason to expand the phrase to encompass dissimilar applications.

The Final Rule’s definition of “covered health care provider” is not remotely similar because it incorporates a new, astonishingly broad definition of “health care services or supplies,” which means “any online service such as a website, mobile application, or internet-connected device that provides mechanisms to track diseases, health conditions, diagnoses or diagnostic testing, treatment, medications, vital signs, symptoms, bodily functions, fitness, fertility, sexual health, sleep, mental health, genetic information, diet, or that provides other health-related services or tools.”<sup>23</sup> Thus, the Commission transforms health care provider,” which both under common usage and in context the statutory provision means entities such as physicians and hospitals, to now include any company “furnishing” a health app.<sup>24</sup> As a

<sup>16</sup> Yates, 574 U.S. at 549.

<sup>17</sup> Id. at 550.

<sup>18</sup> 42 U.S.C. § 1320d(3).

<sup>19</sup> 42 U.S.C. § 1395x(u).

<sup>20</sup> Id. § 1395x(s).

<sup>21</sup> Yates, 574 U.S. at 545 (internal quotation marks omitted).

<sup>22</sup> Majority Statement at 2.

<sup>23</sup> Final Rule at 98.

<sup>24</sup> The SBP explains that an app developer (or any company “furnishing” a health app) would be covered as a health care provider because its health app is a health care service or supply. SBP at 28.

result, the Final Rule creates a tautology: Health app developers may be “vendors of personal health records” by offering an app containing health information that has been created or received by a health care provider, where the health app developer is itself the health care provider that creates or receives that health information by virtue of offering the app.

Notably, even though the Department of Health and Human Services (“HHS”) interprets this same provision of the Social Security Act, HHS—~~notwithstanding the majority’s~~ <sup>25</sup>assertion to the contrary—never interpreted the term “health care provider” to reach the expansive, creative conclusion that the Commission does ~~to~~. <sup>26</sup>The majority’s argument misstates the scope and language of the HIPAA Privacy Rule, which only applies to HIPAA “covered entities” and their “business associates,” i.e., to traditional health care providers that do not include the broad swath of app developers the Final Rule will encompass. Significantly, the majority omits from its characterization of the term “health care” HHS’s ~~illustrations~~ <sup>27</sup>of that term, which highlight the proximity to traditional forms of health care by different kinds of medical professionals:

- (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and
- (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.<sup>28</sup>

The Majority Statement repeatedly says that HHS defines “health care” ~~broadly~~, <sup>29</sup>the language it cites provides no such support.

Aware of this incongruity, the Commission seeks to differentiate ~~its~~ <sup>30</sup>use of “health care provider” from that of “other government agencies.” Yet the Commission provides no explanation why its definitions should differ, particularly where it is unclear whether the Commission has interpretative authority over the Social Security Act’s definition of health care provider and whether other agencies are delegated such interpretative authority.<sup>31</sup>

The Commission also takes troubling liberties with the statute’s definition of “personal health record,” which are evident from a side-by-side comparison of the statute and the Final Rule:

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<sup>25</sup> Majority Statement at 3.

<sup>26</sup> See NPRM at 37823.

<sup>27</sup> 45 CFR §§ 160.102-103.

<sup>28</sup> Id. § 160.103.

<sup>29</sup> Majority Statement at 4.

<sup>30</sup> SBPat 26.

<sup>31</sup> Id. at 13 (noting that HHS interprets these provisions of the Social Security Act in *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 323 (2013) (Roberts, C.J., dissenting) (“When presented with an agency’s interpretation of such a statute, a court cannot simply ask whether the statute is one that the agency administers; the question is whether authority over the particular ambiguity at issue has been delegated to the particular agency.”)).



First, if the majority were correct, from where would it draw the authority to impose this “more than tangentially relating to health” limitation? If Congress in fact commanded us to cover all the apps the majority claims, this extra-textual limitation would be beyond our power to impose.<sup>38</sup> Why, then, does the majority blink in the face of what it understands Congress to have required? There may be good policy reasons not to follow Congress’s language if the majority understands it—wherever it leads, but we do not have power to shortchange Congress’s commands. That even the majority feels compelled to adopt this extra-textual limitation—again, as the majority understands the text—the statute’s reach suggests that the language probably does not mean what the majority says.

The second problem is substantive: What does this language mean? When does an app cross the line between tangentially related to health and more than tangentially related? If a gas station with a loyalty app sells Advil, is the app only tangentially related to health or outside the Final Rule’s purview? If



The FTC is a venerable institution that does vital work to protect consumers and promote competition, thanks to its hardworking and devoted career staff. I commend the staff attorneys, economists, and technologists who worked on the rule for their careful and thoughtful consideration of difficult issues. Ultimately, while I am sympathetic to the majority's goal, I fear that adopting a Final Rule that is irreconcilable with the statute and that puts companies in an untenable position puts the Commission at risk of legal challenges that may undermine the Commission's institutional integrity, and Congress may be reluctant to trust the Commission with other authority—even the much-needed authority to protect the privacy of consumers' sensitive personal information. I therefore respectfully dissent.