No. 102490-8
Court of Appeals No. 84140-8-I

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

STATE OF WASHINGTON,
Respondent/Plaintiff,

v.

JOHNSON & JOHNSON, et al.,
Petitioners/Defendants.

PETITION FOR REVIEW

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I. IDENTITY OF PETITIONERS

Petitioners/Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., and various predecessors and/or affiliated entities ("Janssen") respectfully ask the Court to accept review of the decision designated in Part II of this Petition.

II. DECISION BELOW

Petitioners seek review of the Court of Appeals Division I's July 31, 2023 Opinion reversing a superior court order holding that the State was not immune from discovery of relevant medical claims data because that data was "de-identified" under federal data-privacy regulations (the "Opinion"). A copy of the Opinion is contained in the Appendix at pages A-1 through A-25. The Court of Appeals published the Opinion on September 18, 2023 (Order). A copy of the Order is contained in the Appendix at page A-26.

III. ISSUE PRESENTED FOR REVIEW

Whether the Court should grant review to clarify the standards—applicable to both public and private requests for

health data—for determining that data is "de-identified" and can be disclosed without compromising patient privacy.

IV. STATEMENT OF THE CASE

This petition presents a question of substantial public interest, on which there is little judicial guidance, in the context of one of the State's most high-profile pieces of litigation.

1. In this litigation, the State seeks to hold one manufacturer of niche prescription opioid medications—Janssen Pharmaceuticals—responsible for the entirety of the opioid-abuse epidemic based on a novel reading of nuisance law. Although nuisance is traditionally a property-focused tort, *see Animal Legal Defense Fund v. Olympic Game Farm, Inc.*, 533 P.3d 1170, 1172-73 (Wash. 2023), the State claims that Janssen's marketing of FDA-approved opioid medications caused the opioid-abuse crisis, which the State labels a public nuisance. As relief, the State seeks a cash "abatement" award of $55 billion from Janssen, on the theory that Janssen is jointly-and-severally liable for the epidemic, no matter its degree of responsibility. The

State also contends that Janssen's marketing violated the Consumer Protection Act (CPA).

To defend itself, Janssen sought discovery of information that both the Special Master and the Honorable J. Michael Diaz (then on the King County Superior Court) deemed "without dispute relevant." CP.943 (quotations omitted). The information is de-identified Medicaid claims data with dates-of-service (day, month, year). Based on analyses of similar data from other states, Janssen expects this data to show that a strikingly low percentage of patients prescribed its medications later developed opioid-use disorder (OUD) or other adverse opioid-related outcomes. If Janssen's medication marketing did not drive adverse outcomes, then a significant portion of the State's public-nuisance and consumer-protection theories of liability collapse. And if Janssen's medications did not cause the harms comprising the opioid-abuse epidemic, then it cannot be held responsible for abating that epidemic, even under the State's novel public nuisance theory, let alone be required to foot the entire bill.

2. The data Janssen seeks is subject to federal regulations, commonly known as Part 2, that prohibit the disclosure of information that "[w]ould identify a patient as having or having had a substance use disorder." 42 C.F.R. § 2.12(a)(1)(i). When health information does not contain "information by which the identity of a patient … can be determined with reasonable accuracy," the information is considered "de-identified" and Part 2 does not prohibit disclosure. *Id.* § 2.11. Copies of 42 C.F.R. § 2.11 and 42 C.F.R. § 2.12(a)(1)(i) are contained in the Appendix at pages A-27 through A-35.

In discovery, the State produced its Medicaid claims data with the year-of-service, but unliterally redacted the month and date. Janssen filed a motion to compel the State to produce this data with full dates-of-service, which the Special Master overseeing discovery conditionally granted, concluding that the complete data was both discoverable and relevant. CP.42-43. But the Special Master conditioned that grant on Janssen providing

an expert declaration to confirm that the data is de-identified, CP.42; CP.754-55, under the so-called Expert Determination Method, *see* 45 C.F.R. § 164.514(b)(1). A copy of 45 C.F.R. § 164.514(b)(1) is contained in the Appendix at pages A-36 to A-45.

This petition concerns the proper application of that method for de-identifying data. Under the Expert Determination Method, information is de-identified and can be disclosed if an expert satisfies three conditions:

> 1. The expert must have "appropriate knowledge of and experience with generally accepted statistical and scientifical principles and methods for rendering information not individually identifiable."
>
> 2. Applying those principles, the expert must "determine[] that the risk is very small that the information could be used … to identify an individual who is a subject of the information."
>
> 3. The expert must "[d]ocument the methods and results of [his or her] analysis."

Id.

3. To comply with this requirement, Janssen submitted a declaration from an expert statistician, Dr. Laurentius Marais.

CP.935-41. Federal guidance on the Expert Determination Method explains that the risk of re-identification depends on "the degree to which a data set can be 'linked' to a data source that reveals the identity of the corresponding individuals." CP.145-46. Consistent with this guidance, Dr. Marais explained that, because the de-identified Medicaid dataset does not have patient names, it would need to be linked with some other dataset that has patient names to create a re-identification risk. CP.938. And because the State has already produced its Medicaid dataset with (only) the year of service, disclosing the month- and day-of-service would create an additional re-identification risk only if the dates-of-service in the Medicaid dataset could be linked to the dates-of-service in another dataset containing patient names. CP.938.

After considering, among other things, the "demographic information produced to date" in this litigation and "other publicly accessible information," Dr. Marais concluded that the production of Medicaid data with full dates-of-service presents

no additional re-identification risk because adding dates-of-service to the Medicaid dataset would not allow it to be linked with another dataset with patient names. CP.938. Specifically, Dr. Marais explained that "Janssen does not have access to identified versions of any … complementary data sources"—whether from publicly available information or "data sets produced in this proceeding"—containing patient names that can be linked up to the Medicaid dataset based on the complete dates-of-service. CP.938. Dr. Marais thus satisfied the so-called Expert Determination Method under 45 C.F.R. § 164.514(b)(1), as Judge Diaz found, so federal law does not prohibit disclosing the otherwise de-identified Medicaid dataset with dates-of-service.

Despite nothing in Part 2 providing for a counter-declaration, and despite acknowledging as much, *see* State's Mot. for Discretionary Review 11; *cf.* Appellant's Opening Brief ("Br.") 47, the State hired its own expert, Dr. Latanya Sweeney. Dr. Sweeney hypothesized that the Medicaid dataset could be linked to a dataset containing names, dates-of-death, and certain

demographic information for persons who have died in the State of Washington (the "Death dataset").

Because the Medicaid dataset contains dates-of-service but not names, whereas the Death dataset contains names but not dates-of-service, Dr. Sweeney was forced to manufacture a link between the two datasets to suggest that disclosing dates-of-service in the Medicaid dataset would lead to patient re-identification. To do so, she made two unreasonable and unsupported assumptions. First, she "assum[ed]" that every decedent in the Death dataset died on the last day they received a Medicaid-covered service, and not, for example, the next day or week or month. Br. 26; *cf.* CP.1083 (admitting to using service year "as a proxy for year of death" in evaluating data already disclosed by the State); CP.1086; CP.1089-91. Dr. Sweeney was required to make this assumption to bridge the gap between dates-of-service in the Medicaid data and dates-of-death in the Death data—she assumed those dates were the same. But even this was not enough to show a risk of reidentification. Second,

she also had to assume that every decedent in the Death dataset was on Medicaid. If a decedent was not on Medicaid, then a potential match between the two datasets would not accurately reidentify the decedent. Obviously, not everyone who dies is on Medicaid.

In response, Janssen filed a supplemental declaration from Dr. Marais, which explained (among other things) that Dr. Sweeney's analysis of the Death dataset is fundamentally flawed because it requires nonsensical assumptions. *See* CP.45-47. Specifically, Dr. Marais explained that Dr. Sweeney did not actually identify any unique matches between the two datasets that would make it possible to identify a patient. Rather, she determined how many decedents "*within*" the Death dataset have unique identifying information combinations. CP.47. But there is nothing to link those unique combinations to the Medicaid dataset. As Dr. Marais explained, Dr. Sweeney's suggestion of a link between the two datasets simply "invites the Court to infer—with no actual demonstrated empirical basis—that the complete

dates of death for all decedents could … be related to the complete last service dates in the corresponding decedents' Medicaid claims data." CP.47. For that reason, Dr. Sweeney's hypothetical re-identification of "Medicaid patients by matching them to the" Death dataset "in fact[] demonstrates no actual matching of Medicaid claims data to the WA DOH data." CP.47.

4. The Special Master initially credited Dr. Sweeney's declaration, finding that the risk of re-identification is "substantial" if the de-identified Medicaid data is produced with dates-of-service. CP.276-78. On reconsideration, the Special Master explained that he was denying Janssen's motion to compel for an entirely different reason: he believed that *Dr. Marais* failed to satisfy the Expert Determination Method. CP.524-25.

On April 13, 2022, Judge Diaz sustained Janssen's objection and granted Janssen's motion to compel. CP.942-47. Judge Diaz "agreed with the Special Master's conclusion that the information sought is without dispute 'relevant.'" CP.943. And

he found "that the Defendants' expert's declaration is compliant with … § 164.514(b)(1)." CP.945.

5. The Court of Appeals reversed. It concluded that the Expert Determination Method was not satisfied, seemingly for two reasons: (i) that Dr. Marais "did not review or consider the consequences of the Death Dataset before opining" that the re-identification risk associated with the data Janssen seeks is very small; and (ii) that he "did not document having applied principles and methods for rendering information not individually identifiable." App'x, p. 19.[1] The Court did not review these questions of fact for clear error, nor did it defer to Judge Diaz's exercise of discretion in resolving this dispute. Instead, its opinion suggests that Judge Diaz *per se* abused his discretion because the Expert Determination Method requires an expert to list out all datasets he or she considered and to perform

[1] The Court of Appeals also purported to identify other defects in the trial court's decisions, but none is germane to the question whether Dr. Marais satisfied the Expert Determination Method. *Infra* at 28-30.

"calculations" or "computations" of the risk of re-identification, Br. 42, although the opinion is fundamentally unclear, *see infra* at 22-25.

The State then asked the Court of Appeals to publish its opinion. As grounds, the State argued that "proper application" of Part 2 "is an issue[] of continuing and substantial public interest." Mot. to Publish 4-5 (quotations omitted). And the State argued that there is an urgent need for judicial clarification of the law because the "lack of [judicial] guidance results in misunderstanding (or out-and-out disregard) of the statutory and regulatory requirements." *Id.* at 2. On September 18, 2023, the Court of Appeals granted the State's Motion to Publish.

This timely petition for review follows. *See* RAP 13.4(a).

V. ARGUMENT

A. The Requirements For De-identification Under The Expert Determination Method Are An Issue Of Substantial Public Importance.

Both Janssen and the State agree that "the proper application" of Part 2—and in particular, the Expert

Determination Method—"is an issue of continuing and substantial public interest." Mot. to Publish 4 (quotations omitted). Both parties also agree that Washington decisional law "provides [no] guidance on the limits of a trial court's discretion in determining when data is de-identified" under the Expert Determination Method, and that this "lack of guidance results in misunderstanding … of the statutory and regulatory requirements." *Id.* at 2. But instead of filling this void, the decision below exacerbates it, providing scant guidance on the legal requirements for satisfying the Expert Determination Method. This Court should grant discretionary review to resolve this important question and bring much needed clarity to the law.

1. The proper application of Part 2—including the Expert Determination Method—is a question of substantial public interest. *See* RAP 13.4(b). The State successfully petitioned the Court of Appeals to publish its opinion largely on this basis. *See* Order (Sept. 18, 2023); Mot. to Publish 4-5. And the only other Washington appellate court to have interpreted

Part 2 likewise held that proper application of the Part 2 requirement at issue there was an "issue[] of continuing and substantial public interest." *Daybreak Youth Servs. v. Clark Cnty. Sheriff's Off.*, 19 Wn. App. 2d 879, 882, 498 P.3d 571 (2021).

Indeed, proper application of the Expert Determination Method is an issue that has far-reaching consequences. Part 2 applies any time a party seeks disclosure of protected health information—including data requests via a subpoena (as here and in other pending opioid litigation in Washington, *see* Mot. to Publish 3), a warrant (as in *Daybreak*, 19 Wn. App. 2d 879), or in any other litigation or law enforcement context. The rules governing the Expert Determination Method therefore impact not only patients seeking OUD treatment but also providers, litigants, public health agencies, law enforcement, and virtually any other entity seeking or holding records covered by Part 2. Nor is this issue limited to litigation. The Expert Determination

Method may be implicated *any* time a public or private entity seeks covered information.

That the question presented will affect public entities seeking and holding protected data is reason enough to grant review. That it also applies more broadly—to public and private parties, within and without litigation—confirms the need for this Court's guidance.

This case illustrates the importance of the Expert Determination Method. The State seeks to hold Janssen responsible for the *entirety* of the opioid-abuse epidemic based on a novel reading of public nuisance law. *Supra* at 2-3. The de-identified Medicaid claims data Janssen seeks is critical to its defense—both the Special Master and Judge Diaz agreed the data is "without dispute relevant." CP.943 (quotations omitted). Data showing that patients prescribed Janssen's medications experienced comparatively fewer adverse opioid-related outcomes than patients who took other manufacturers' opioid medications is relevant to causation, an element of the State's

nuisance claim, and to the likelihood of deception that underlies its CPA claim. *See Tiegs v. Watts*, 135 Wn.2d 1, 15, 954 P.2d 877 (1998); WPI 380.03; *State v. TVI, Inc.*, 1 Wn.3d 118, 524 P.3d 622, 635 (Wash. 2023). Any nuisance-abatement remedy, moreover, must account for the negligible role Janssen's medications played in bringing about opioid-related harm. *See City of Benton City v. Adrian*, 50 Wn. App. 330, 340, 748 P.2d 679 (1988); Restatement (Second) of Torts § 840E, cmt. b. If Janssen's medications did not cause the harms comprising the opioid-abuse epidemic, then it cannot be held liable for the epidemic's costs, much less all of them.

2. Despite the overriding importance of the requirements under the Expert Determination Method, Washington decisional law provides no guidance to public and private entities seeking disclosure of de-identified data. As the State has correctly observed, "*no* other Washington decision," besides the decision below, "provides guidance" on the legal

rules for satisfying the Expert Determination Method. Mot. to Publish 2.

This lack of guidance has significant real-world consequences. On the one hand, patient privacy is compromised when the Expert Determination Method is not properly satisfied. But on the other hand, important public and private interests are stymied when parties cannot access data to which they are entitled. In this case, for instance, the State is relying on a misinterpretation of the Expert Determination Method to block Janssen from obtaining information that the lower courts agreed is relevant to its defense against the State's $55 billion claim for "abatement." In other circumstances, law enforcement may be prevented from obtaining critical information by the misapplication of the Expert Determination Method. Both parties thus agree that "clarity" is "needed." *Id.*

The Court of Appeals' published decision only adds to the confusion. Purporting to apply an abuse-of-discretion standard, the Court held that Judge Diaz erred in concluding that Dr.

Marais satisfied the Expert Determination Method. App'x, pp. 18-19. But apart from resolving issues that are not actually relevant to this dispute, *see infra* at 28-30, the Court did not explain what the Expert Determination Method requires and thus how Judge Diaz abused his discretion in applying it.

For instance, the Court concluded that "Dr. Marais did not document having applied principles and methods for rendering information not individually identifiable." App'x, p. 19. Setting aside for the moment that this appellate factfinding is wrong, *infra* at 20-21, the Court never explained what kind of documentation the Expert Determination Method requires in the first place. Was Dr. Marais required to perform "calculations" and "computations," as the State argued? *See* Br. 42. Would something else suffice? The Court's opinion leaves parties without the instruction they need to comply with the Expert Determination Method and trial courts without the guidance they need to enforce its requirements.

Likewise for the Court's holding that Dr. Marais "did not review or consider the consequences of the Death Dataset before opining" that disclosing the health data here would not risk re-identification. App'x, pp. 18-19. Did the Court mean to suggest that the Expert Determination Method requires an expert to recite every publicly- and privately-available source of information that could theoretically be lined up against the data set in question? Or was the defect one of timing? After all, Dr. Marais made clear in his first declaration that he considered the "data sets produced in this proceeding," CP.939, and expressly referenced the Death dataset in his second declaration, CP.46-47.

The missing element in the Court of Appeals' opinion, in other words, is the *reason* Judge Diaz abused his discretion in finding that Dr. Marais's declarations satisfied the Expert Determination Method. Parties seeking to comply with the Expert Determination Method have no more guidance on how to do so after the Court's decision than they did before. The same goes for trial courts who are tasked with applying that method.

B. The Decision Below Is Wrong.

To the extent it is possible to discern any legal rules from the Court of Appeals' opinion, those legal rules are wrong. In particular, the opinion is likely to be read to require an expert to (i) expressly list every dataset considered and (ii) "document … calculations" and "computations" used to de-identify individual health information. *See* App'x, p. 19; Br. 42; *supra* at 11-12. Neither requirement finds support in the federal regulations or Department of Health and Human Services ("HHS") guidance explaining them.

1. The Court of Appeals first concluded Dr. Marais's declaration was insufficient because it "reveals that he did not review or consider the consequences of the Death Dataset" in forming his opinion that there is no re-identification risk. App'x, p. 19. As an initial matter, that appellate fact-finding is clearly wrong—and impermissible, since appellate courts do not find facts. *See Quinn v. Cherry Lane Auto Plaza, Inc.*, 153 Wn. App. 710, 717, 225 P.3d 266 (2009). Dr. Marais's initial declaration

made clear that he considered the "data sets produced in this proceeding," which include the Death dataset. CP.938-40.[2] And his second declaration expressly explained that the Death dataset would not allow for re-identification because it cannot reliably be lined up against the Medicaid dataset based on dates-of-service (because the Death dataset doesn't contain dates-of-service). CP.45-47. So there was no basis for the Court of Appeals to say Dr. Marais did not consider the Death dataset—because he did.

The Court of Appeals must have believed that the Expert Determination Method required Dr. Marais to expressly list out all the data sets he considered in his first declaration and that any data sets referenced in a later declaration could not cure that

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[2] In his initial declaration, Dr. Marais expressly cited Washington Labor & Industries Workers' Compensation data ("L&I") and the Washington Public Employees Benefits Board Program data ("PEBB"). CP.939. He chose these examples because the State mentioned them in meet-and-confer discussions. But Dr. Marais elsewhere made clear that his analysis was not limited to these datasets. He considered all of the "data sets produced in this proceeding" and "publicly available information." CP.938-40.

supposed error. There is zero support for such a rule, which explains why the Court cited nothing—no regulation, no case, no guidance—in support of its holding. Indeed, the HHS Office for Civil Rights ("OCR") guidance expressly contemplates that the "process [under the Expert Determination Method] may require several iterations" before reaching an acceptable solution, CP.143—which confirms that subsequent analyses performed by the expert can suffice.

2. The Court of Appeals also faulted Dr. Marais because he did not "document having applied principles and methods for rendering information not individually identifiable." App'x, p. 19. The Court did not explain what this means or what Dr. Marais should have done differently to satisfy the Expert Determination Method. In its briefs, the State argued that Dr. Marais was required to employ mathematical "calculations" or "computations," Br. 42, and the Court's decision can be read to endorse this rule. But federal guidance does not impose a

mathematical "risk assessment calculation[]" requirement. Br. 34-35.

Rather, OCR is very clear that the Expert Determination method "does *not* require a particular process for an expert to use to reach a determination that the risk of identification is very small." CP.143; *see also* CP.147 ("The de-identification standard does not mandate a particular method for assessing risk."). OCR does "require that the methods and results of the analysis that justify the determination be documented and made available to OCR *upon request*," CP.143. (emphasis added)—a requirement Dr. Marais satisfied, CP.935-40; CP.45-47, though OCR has never requested his declarations. Nothing in the Rule or the OCR guidance, by contrast, requires an expert's declaration to contain mathematical calculations. (Which explains, again, why the Court of Appeals again cited nothing in support of its decision.)

Although OCR does not require experts to employ any particular methods, it does suggest basic principles for determining that a dataset's re-identification risk is very small.

Dr. Marais's declaration applied the same basic principle as OCR's guidance—namely, that unless there is another dataset with names that can be linked to the Medicaid dataset, there is no risk of re-identification.

As OCR puts it, the re-identification risk depends on "the degree to which a data set can be 'linked' to a data source that reveals the identity of the corresponding individuals." CP.145. If one dataset (like the Medicaid dataset here) does not include identifying information, it would have to be linked with another dataset that does include identifying information to give rise to a privacy risk. "Without such a data source, there is no way to definitively link the de-identified health information to the corresponding patient." CP.145-46.

Simply naming another data source with identifying information about potentially overlapping individuals is not enough. There must be a way to link the information in the two datasets to give rise to a risk of re-identification: "we need a mechanism to relate the de-identified and identified data sources.

Inability to design such a relational mechanism would hamper a third party's ability to achieve success [at identifying patients] to no better than a random assignment of de-identified data and named individuals." CP.146.

Linkage, OCR explains, "is a process that requires the satisfaction of certain conditions." CP.146. Identifying patients from a dataset (like the Medicaid dataset) with no personal identifying information thus requires, at a minimum: (i) another dataset or source of information with identifying information; and (ii) overlap between the two that provides a "way to definitively link the de-identified health information to the corresponding patient." CP.146. If these "conditions" are not satisfied, there is no risk of re-identification.

Applying that principle, Dr. Marais explained that there is no "linking" mechanism in this case—the service and prescription dates in the Medicaid data would not allow Janssen to link that data with any naming "data set produced in the litigation" or "publicly accessible" dataset. CP.938. "Janssen

does not have access to identified versions of any" dataset that could be used "to link records from the … Medicaid data" if the full prescription and service dates were provided. CP.938. Again, that is because the Medicaid dataset does not have patient names and there is no other dataset (including the Death dataset) that has names and dates-of-service. CP.47; CP.938. Thus, Dr. Marais correctly concluded, there is no risk to patient privacy here. And he documented the principles he applied—the very same ones contained in federal guidance. The Court of Appeals erred in concluding otherwise because it manufactured additional requirements that Dr. Marais did not satisfy—requirements nowhere present in either the Rule or the OCR guidance.[3]

[3] Although irrelevant for the reasons discussed below, Dr. Sweeney's declaration actually proves this point. All Dr. Sweeney did was calculate the supposed re-identification risk based on Medicaid year-of-service data the State already voluntarily produced in this litigation. Her only supposed assessment of risk associated with disclosing dates-of-service depended on assuming that (1) every person in Washington who died was on Medicaid at their time of death and (2) had a claim for Medicaid services on the day they died—assumptions that defy reason.

3. The Court of Appeals purported to identify several other errors in Judge Diaz's decision granting Janssen's motion to compel. *See* App'x, pp. 17-21. But none of those asserted errors is relevant to the question of whether *Dr. Marais* satisfied the Expert Determination Method.

The Court of Appeals faulted Judge Diaz for attributing to Dr. Marais a calculation he did not perform. *See* App'x, p. 19. The calculation at issue actually pertains to a portion of Dr. Sweeney's declaration and Dr. Marais's response. Dr. Sweeney purported to evaluate the risk of re-identification from comparing the Death dataset to a subset of the Medicaid data the State already produced—hospice patients on Medicaid. CP.1081. On the "assumption" that the last year a hospice patient received any service from Medicaid was the year he or she died, Br. 26, Dr. Sweeney asserted that overlap between the Death dataset and the hospice data subset—i.e., the year of death and year of last service—made it possible to identify a certain number of

patients. CP.1083 (using service year "as a proxy for year of death"); *see also* CP.1086.

Assessing the total re-identification risk Dr. Sweeney hypothesized, in turn, requires choosing the right denominator—i.e., either the total Medicaid patient population (4.5 million) or the subset of hospice patients on Medicaid (23,013). *See* App'x, pp. 19-20; CP.867; CP.869. Using the smaller denominator means the risk is higher, and vice versa. The Court of Appeals faulted Judge Diaz for concluding that Dr. Marais suggested the former while Dr. Sweeney employed the latter. App'x, pp. 19-20.

That conclusion is irrelevant for three reasons. *First*, the calculation pertains only to Dr. Sweeney's analysis, but the content of her declaration has no bearing on whether *Dr. Marais* satisfied Part 2. *Supra* at 27. The State correctly recognized that Dr. Sweeney's declaration is outside Part 2's prescribed process for the Expert Determination Method altogether. *See* State's Mot. for Discretionary Review 11; *cf.* Br. 47.

Second, Dr. Sweeney's calculation says nothing about the risk of re-identification posed by *adding* the day- and month-of-service and prescription information to the information already included in the de-identified Medicaid data the State has produced—which is the only issue on appeal. The question here is whether the addition of full service dates would allow Janssen to re-identify patients with accuracy. Dr. Sweeney's analysis of hospice data did not evaluate that question. Instead, her analysis pertained to the risk of re-identifying patients *in the data the State had already produced*. *See* App'x, p. 20 (recognizing this fact). The State even said that this "denominator problem" is not relevant to the issue on appeal. *See* Br. 50-51.

Third, the denominator for this calculation does not matter because the numerator of patients who can be re-identified in the hospice data (that the State produced without objection) is zero. Dr. Sweeney concluded otherwise—i.e., that some patients could be re-identified—only by assuming that, where certain demographic data matched, every patient died the last year they

received Medicaid service, which of course is an unreasonable assumption. *Supra* at 8-10.

The Court of Appeals also held that Judge Diaz erred in faulting the Special Master for assessing whether there is "any risk" of re-identification, rather than applying the "very small risk" standard established in 45 C.F.R. § 164.514(b)(1). App'x, p. 18. That supposed error has nothing to do with whether Dr. Marais satisfied the three requirements of the Expert Determination Method. Dr. Marais concluded there is "no way that Janssen could use the complete date information that it seeks to reidentify the Medicaid claims data in this litigation" because it does not have access to any data source with names that can reliably be linked up to the Medicaid dataset. CP.938. In other words, Dr. Marais's analysis passes muster regardless of whether the Expert Determination Method imposes a "no risk" or "very small risk" standard.

In sum, these asserted errors do nothing to detract from the significant flaws in the Court of Appeals' analysis. Indeed, that

the Court ventured well beyond the requirements of the Expert Determination Method suggests that it did not fully grasp the data privacy question it was being asked to decide. It was not being asked to grade Judge Diaz's opinion; its sole task was to determine whether Judge Diaz correctly found that the Expert Determination Method's three requirements were satisfied. On that question, the Court's published decision provides litigants and trial courts little or no guidance, and what scant guidance it may provide is flawed and needs immediate correction.

VI. CONCLUSION

For all the foregoing reasons, the Court should grant discretionary review.

This document contains 4,993 words, excluding the parts of the document exempted from the word count by RAP 18.17.

DATED this 18th day of October, 2023.

Respectfully submitted,

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APPENDIX

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Division I
State of Washington

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

STATE OF WASHINGTON, Appellant, v. JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; and XYZ Corporations 1 through 20, Respondents.	No. 84140-8-I DIVISION ONE UNPUBLISHED OPINION

COBURN, J. — The State sued Johnson & Johnson and Janssen Pharmaceuticals (collectively Janssen), claiming that they violated the Consumer Protection Act and created a public nuisance by contributing to the opioid crisis in Washington. During discovery, the State produced data from a Medicaid claims database consistent with the Health Insurance Portability and Accountability Act (HIPAA) disclosure practices, which meant only the years of claims were included, instead of full dates. Janssen moved to compel the production of the specific days and months related to service and prescription dates. A Special Master agreed with the State that releasing full dates created a risk of re-identifying Medicaid patients that was

not small enough to be acceptable under HIPAA. The trial court disagreed, overruled the Special Master, added its own parameters related to the release of data, and granted the motion to compel. A commissioner of this court granted the State's request for discretionary review. We reverse.

BACKGROUND

The State Attorney General filed this lawsuit against Janssen[1] and affiliated defendants alleging that they violated the state's Consumer Protection Act and created a public nuisance regarding its manufacture and marketing of pharmaceutical opioids. Discovery was presided over by a court-appointed Special Master. A Special Master is permitted under CR 53.3 to provide independent assistance to the court in resolving complex discovery issues. 4 ELIZABETH A. TURNER, WASHINGTON PRACTICE: RULES PRACTICE CR 53.3 author's cmt. 1 (7th ed. 2021).

During discovery, the State produced 11 years of data from a database of all Medicaid claims in the state maintained by the Washington Healthcare Authority (HCA). The database contains health information for millions of Washington residents. The data provided to Janssen included the year in which Medicaid services were provided, but not the month or the day of the service, in accordance with HCA's typical disclosure practices.

In passing HIPAA in 1996, Congress recognized the need for strict privacy protections for health information, authorizing the United States Department of Health and Human Services (DHHS) to promulgate regulations to put protections in place,

[1] The State alleges that Johnson and Johnson is the only company that owns more than 10 percent of Janssen Pharmaceuticals' stock and corresponds with the Federal Drug Administration regarding Janssen's products.

codified at 45 C.F.R. §§ 160 and 164. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936. The regulations apply to "covered entities," including health plans and health care providers transmitting any health information electronically. 45 C.F.R. § 164.104(a)(1), (3). The rule defines protected health information to mean "individually identifiable health information"—that is, health information "[t]hat identifies the individual" or "[w]ith respect to which there is a reasonable basis to believe the information can be used to identify the individual." 45 C.F.R. § 160.103. Covered entities are generally prohibited from using or disclosing protected health information, with a limited number of exceptions outlined in 45 C.F.R. § 164.502.

DHHS provides standards and requirements related to "[d]e-identification of protected health information." "Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information." 45 C.F.R. § 164.514(a). Under "Implementation specifications: Requirements for de-identification of protected health information," a covered entity "may determine that health information is not individually identifiable health information only" through two methods: "Safe Harbor" or "Expert Determination." 45 C.F.R. § 164.514(b).

The Safe Harbor method requires removing 18 identifiers listed in 45 C.F.R. § 164.514(b)(2)(i). 45 C.F.R. § 164.514(b)(2). That list includes "[a]ll elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death." 45 C.F.R. § 164.514(b)(2)(i)(C).

Under the Expert Determination method, a covered entity may determine that health information is not individually identifiable health information only if

> (1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
>
> (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
>
> (ii) Documents the methods and results of the analysis that justify such determination.

45 C.F.R. § 164.514(b)(1).

The DHHS's Office of Civil Rights (OCR) issues guidance on complying with de-identification procedures, including the expert determination method. This guidance notes that there is no certain degree or certification program for use in designating an expert, but that expertise may be gained through relevant education and experience generally in mathematics, statistics, or scientific domains. It also notes that

> There is no explicit numerical level of identification risk that is deemed to universally meet the "very small" level indicated by the [Expert Determination] method. The ability of a recipient of information to identify an individual (i.e., subject of the information) is dependent on many factors, which an expert will need to take into account while assessing the risk from a data set . . . As a result, an expert will define an acceptable "very small" risk based on the ability of an anticipated recipient to identify an individual.

The guidance also states "OCR does not require a particular process for an expert to use to reach a determination that the risk of identification is very small. However, the Rule does require that the methods and results of the analysis that justify the determination be documented." The guidance also observed general principles (replicability, data source availability, distinguishability, assess risk) used by experts in

the determination of the identifiability of health information and cited published research by Dr. Latanya Sweeney, PhD, among others. Though not a definitive list, the principles serve as a starting point and "experts are advised to consider how data sources that are available to a recipient of health information . . . could be utilized for identification of an individual." The guidance explained that experts, when evaluating identification risk, often consider the degree to which a data set can be linked to a data source that reveals the identity of the corresponding individuals. To do so, experts consider 1) that the de-identified data are unique or distinguishing, 2) the existence of a naming data source, including publicly available databases, and 3) the existence of a mechanism to relate the de-identified and identified data sources.

After receiving the Medicaid data that included 1,835,136,898 distinct records, Janssen moved the court to compel the State to supplement the Medicaid claims data with the month and day of the services and prescriptions. Janssen argued that it needed the data to determine the "extent to which prescriptions for Janssen opioid medications preceded diagnoses for opioid use disorder" as part of its defense.

The State objected. It submitted a declaration from the Privacy Officer of the Washington Healthcare Authority (HCA) explaining that HCA is a covered entity subject to the requirements of HIPAA and 42 C.F.R. part 2, which regulates the disclosure of information related to federally subsidized substance use disorder treatment. The State argued that there are two ways that Janssen can legally obtain information protected under part 2: with individual patient consent, or under a court order finding good cause for disclosure after every impacted patient receives notice and an opportunity to be heard. See 42 U.S.C. § 290dd-2(b)(1),(b)(2)(C); 42 C.F.R. § 2.64(b), (d). The State

argued that, despite having raised these issues with Janssen, Janssen had not offered a plan for identifying the millions of impacted patients and obtaining their consent, nor had it offered any proposal to give notice to these impacted patients. The State argued that granting a motion to compel HCA to disclose full dates associated with individual patients would cause HCA to violate federal law under HIPAA and 42 C.F.R. part 2.

The Special Master held a hearing on the motion in October 2021 and provisionally granted Janssen's motion, subject to Janssen providing "expert certification to the special master that the disclosure of this information does not have the potential for re-identification or for reverse engineering to disclose the identity of the individuals for whom the data is disclosed, and is HIPAA-compliant."

Janssen submitted a declaration from Dr. M. Laurentius Marais, PhD, which stated that there was virtually no risk of re-identification of individuals should the data be supplemented. The State submitted an expert report by Dr. Latanya Sweeney, PhD, who refuted Dr. Marais' declaration as containing incorrect statements. Dr. Sweeney demonstrated how full dates in the Medicaid Dataset "would allow it to be joined with other publicly available and privately held information, thus allowing sensitive information on individuals in the Medicaid Dataset to be re-associated with named individuals."

Janssen Expert Dr. Marais

Dr. Marais works for a "consulting firm that specializes in applied mathematical and statistical analysis" and holds "a PhD degree and master's degrees in business administration, mathematics, and statistics from Stanford University." He has several decades of experience in applying and reviewing mathematical and statistical theory

and methods. He has taught and conducted scholarly research at the University of Chicago and Stanford University. Dr. Marais lists his areas of expertise as "the uses of biostatistical and epidemiological methods to draw conclusions from data concerning the rates of and risk factors for health effects, including the analysis of data on the efficacy of and adverse events associated with pharmaceutical drugs." Janssen retained Dr. Marais to conduct similar work he had previously performed for Janssen in California – to statistically analyze the de-identified medical claims data by locating the date of an opioid use disorder diagnosis for each patient and analyzing data prior to that diagnosis to determine whether the corresponding pharmacy claims data reflected any opioid prescription for the same patient. In response to the Special Master's order, Janssen submitted a declaration from Dr. Marais specifically addressing concerns about re-identification.

Dr. Marais declared he was "competent to testify about the matters set forth herein because I have either personally observed such matters or have formed opinions within my areas of professional expertise concerning such matters." Dr. Marais explained in his declaration:

> 8. Assuming Plaintiff did not hold the same level of concern about its previous production of de-identified Medicaid data, Plaintiff's current elevated concern must arise from some hypothetically increased vulnerability to re-identification based on month and day information in addition to the calendar-year information produced previously. Based on my education, pertinent experience, and pertinent background knowledge, it is my opinion that the re-identification risk associated with the production Janssen seeks, whether arising from the completed dates alone or in combination with other demographic information produced to date, or with other publicly accessible information, is *de minimis*, if indeed any nonzero risk exists at all.
>
> 9. I base this opinion on the simple fact that any risk of re-identification from the additional month and day information Janssen is

> seeking would have to arise from the purely hypothetical notion of using complete service and dispensing dates to link records from the de-identified Medicaid data disclosed by Plaintiff to dated records from another, complementary data source that could reveal the identities of individual patients (a so-called "naming data source"). But Janssen does not have access to identified versions of any such complementary data resources. Indeed, patient names and other identifying information have routinely been removed from analogous data sets in other opioid litigation, and I understand that, to the extent Janssen seeks any *potentially* identifying, supplementary information in this litigation, it has indicated it too would be produced in a de-identified form. Accordingly, there is simply no way that Janssen could use the complete date information that it seeks to re-identify the Medicaid claims data in this litigation.

Dr. Marais went on to explain that there is no realistic prospect that Janssen could re-identify patients using two data sets produced in the litigation provided by the Washington Labor & Industries Workers Compensation (L&I) and Washington Public Employees Benefits Board Program (PEBB). Dr. Marais reasoned that "neither the L&I nor the PEBB data (nor any other data set produced in this litigation) include individually identifying information." Dr. Marais concluded that "the demographic descriptors included in these data sets (year of birth, gender, race, marital status, and three-digit ZIP code) are insufficient to establish that records drawn from different data sets but having identical demographic descriptors actually represent the same individual patient, even when these combinations of descriptors are unique in the data sets where they appear." He further opined that "even if [demographic indicators] *did* happen to represent the same patient, this fact per se would still not identify that patient (because the patient data sets produced in this proceeding simply do not contain a key to individually identifying information, either individually or collectively, with o*r* without the complete service dates that Janssen seeks)." Dr. Marais said that this reasoning "supports my opinion that the incremental re-identification risk associated with the

production Janssen seeks is essentially *nil*."

Dr. Marais asserted that he needed the complete date of every medical service and prescription fill event in order for him to conduct his analysis, but suggested that the State could "re-produce" the Medicaid data without demographic variables such as birth year, gender, marital status and race.

Dr. Marais further concluded that "there is no basis for supposing" that full Medicaid service dates would contain information that overlapped with service or pharmacy claim records in the workers' compensation or public employee benefits program datasets available to Janssen. Dr. Marais did not document any method of applying statistical and scientific principles and methods to support his opinion that the risk of re-identification is essentially nil.

State's Expert Dr. Sweeney

The State's expert, Dr. Sweeney is the director and founder of the Data Privacy Lab and Public Interest Technology Lab at Harvard University, where she is also a professor. Prior to her current position she was a Chief Technology Officer at the United States Federal Trade Commission, was a commissioner on the U.S. Evidence Based Policy Making Commission, and a professor of Computer Science, Technology, and Policy at Carnegie Mellon University. Dr. Sweeney earned a PhD in computer science from the Massachusetts Institute of Technology. Alongside this experience, Dr. Sweeney also lists extensive experience specific to data privacy in medical records, including the identification of re-identification risks and privacy vulnerabilities in publicly available medical data. Her work includes re-identification of Washington State health data in 2015 using blotter stories from archived newspapers and publicly available

health data.[2] Through this method, Dr. Sweeney was able to learn sensitive information about patients, such as drug and alcohol abuse and sexually transmitted diseases, none of which had anything to do with the news stories. Dr. Sweeney's work is cited in the preamble to HIPAA and in other federal regulations.

The State retained Dr. Sweeney to review Janssen's request for the creation of a version of the de-identified Medicaid Dataset that has full dates for services and prescription refills, and to assess privacy risks related to the disclosure of the Medicaid Dataset. This work is consistent with many other projects she has worked on to demonstrate privacy vulnerabilities. Dr. Sweeney cited her own work as well as published papers reporting re-identification experiments. She also reviewed Dr. Marais' declaration and noted that it did not provide any evidence or detailed analysis, and did not address a large body of evidence contrary to his opinion.

Dr. Sweeney conducted an analysis using the same information that had been provided to Janssen, the Medicaid Dataset as well as the Death Dataset, which is from the official death registry for the State of Washington. Dr. Sweeney explained that while not all decedents who appear in the Death Dataset are in the Medicaid Dataset, almost all decedents in the Medicaid Dataset should be in the Death Dataset.[3] Dr. Sweeney described the Death Dataset as "semi-publicly available," noting that the term is used when there is an associated cost for acquisition that limits its availability or requires a lengthy or involved review or application process that limits access. She first measured the identifiability of the Death Dataset, because doing so "describes the overall ground

[2] Latanya Sweeney, *Only You, Your Doctor, and Many Others May Know*, TECH. SCI. (Sept. 28, 2015), https://techscience.org/a/2015092903 [https://perma.cc/K3Q5-L3P2].

[3] The Death Dataset is from the years 2007 through 2017.

truth of the identifiability of death data in subsets that could link to it, such as the Medicaid Dataset." Dr. Sweeney started with the Death Dataset "because matches of records in the Medicaid Dataset to records in the Death Dataset puts names and addresses, as well as Social Security numbers, to the health data." Dr. Sweeney further explained:

> If each decedent record in the Medicaid Dataset matches lots of other records in the Death Dataset ambiguously, then the identifiability of the decedent records in the Medicaid Dataset is low. On the other hand, if decedent records in the Medicaid Dataset match one or few of the name-bearing records in the Death Dataset, then the identifiability of the Medicaid Dataset is high. The following experiment reports how low or high the identifiability can be based on the identifiability of the Death Dataset.

Through progressive experiments Dr. Sweeney was able to demonstrate how 191 hospice patients in the Medicaid Dataset uniquely matched 191 named records in the Death Dataset. Dr. Sweeney focused on hospice patients in the Medicaid claims reasoning that patients who receive services at hospice facilities will soon decease and can expect their claims for hospice to appear in the Medicaid Dataset and death to appear in the Death Dataset. Dr. Sweeney compared the 23,013 records for distinct patients who received hospice care that contained year of birth, gender, and the first three digits of their zip code (3-digit zip code). Then by using the last year of hospice service as a proxy for year of death, Dr. Sweeney, found 191 unique matches in the Death Dataset. This constituted a .83 percent match of the 23,013 hospice records. Observing that HIPAA allows health data to be shared that has more than a zero risk, Dr. Sweeney stated "in the case of HIPAA, the risk was quantified experimentally to be acceptable at 0.04% and 0.02% for [unique one to one matches] based on dates in years and only the first three digits of the ZIP code." When Dr. Sweeney added

race/ethnicity data to the analysis, the unique matches increased to 1,275. Dr. Sweeney opined that if Janssen were to obtain the full dates for service claims in the Medicaid Dataset and if the full date of the last day of service for hospice patients matched the date of death, then identifiability would increase further. When using month, day, and year of death, year of birth, gender, 3-digit zip code and race/ethnicity, Dr. Sweeney was able to identify 90 percent of the 574,058 records in the death Dataset as unique. Dr. Sweeney opined that "Defendant's request for complete dates in the Medicaid Dataset would allow inferences that can put names to a substantial number of records in the Medicaid Dataset."

Dr. Sweeney explained that the "risk is not limited to the Death Dataset alone. There are a multitude of possibilities, especially considering publicly and privately held data." Dr. Sweeney concluded that

> Defendant's request does not seem to understand the privacy risks involved in releasing personal health information under today's standards. The fact is that grave risks exist in the data as proposed for release, even without lowering the standard to include complete and full dates of medical services and prescription refills. Lowering the standard would not even adhere to federal and best practices standards for the sharing of personal health.

Dr. Sweeney explained that it is not impossible to anonymize the data and that the proper way requires the use of "scientifically proven methods, not ad hoc guess work (see Declaration of Defendant's expert). [Janssen]'s request comes nowhere close to meeting those established standards or otherwise assuring individuals whose sensitive health information is in the Medicaid Dataset cannot be re-identified."[4]

[4] Dr. Sweeney's report discussed two of methods of anonymizing data: k-anonymity and differential privacy.

Alongside the submission of Dr. Sweeney's report, the State submitted a declaration from Christopher Purdy of Celerity Consulting Group explaining that an alternative to providing Janssen with the full dates of service, it could provide a "sequenced" dataset. Purdy explained that the sequenced dataset "would indicate the sequence of [Medicaid claims] events within a given year without revealing any day and month information for those events." He explained that the group had previously provided sequenced datasets of L&I data for use in discovery production in the State's litigation with other opioid manufacturers.

The Special Master held another hearing in January 2022, allowing the parties to argue their positions regarding the expert opinions. The Special Master ordered the State to provide sequencing of the Medicaid Dataset, but denied Janssen's request to supplement the Medicaid Dataset with month and date of servicing and prescription filling. The Special Master reasoned that it was persuaded from Dr. Sweeney's opinion that re-identification is a substantial risk if this additional information is produced by the State.

The Special Master held an additional hearing in February 2022 after Janssen moved for reconsideration of his prior ruling denying the motion to compel the production of full Medicaid service dates. The Special Master ruled that both Dr. Marais and Dr. Sweeney were qualified experts under 45 C.F.R. § 164.514(b)(2). The Special Master then concluded that it found "Dr. Marais' conclusions stating such a risk is de minimis if indeed any nonzero risk at all is ipse dixit" and that Janssen did not meet its burden of showing the "risk is very small" under §164.514(b).

Janssen then filed an objection to the Special Master's ruling and order denying its motion to compel the supplemental Medicaid claims data. Janssen asserted in the motion that Dr. Sweeney had incorrectly calculated the risk of re-identification stating,

> Dr. Sweeney's analyses of DOH mortality data were limited to identifying *potential* matches (not reasonably accurate matches) in a limited subset of hospice patients' Medicaid data. And she found that just 191 hospice patients in the Medicaid data had a birth year, gender, and a three-digit zip code that corresponded to the same demographic information for a decedent in the DOH death data. Even assuming those were true matches (an assumption unsupported by the record), Dr. Sweeney showed nothing more than a re-identification risk of 0.0004% (191 of over 4.5 million Medicaid patients).

The trial court, without oral argument,[5] sustained Janssen's objection and reversed the Special Master's ruling. The trial court believed the State and Special Master had applied an incorrect standard and each had suggested that "any risk of re-identification is unacceptable." The trial court noted that neither the State nor Special Master had addressed "how the Court could minimize, if not entirely eliminate, the risk of re-identification, and the burden to the State." The trial court specifically found that the expert opinion of Dr. Marais provided by Janssen "is compliant with the certification requirement in 45 C.F.R. § 164.514" and that "the most probative portion of [Dr. Marais'] analysis largely boiled down to one similar to the State's expert's, but with a different denominator." The court then concluded there was no justification of using the total number of hospice patients as opposed to the total number of Medicaid patients, followed the change in the formula proposed in Janssen's brief and found that "the resulting risk of re-identification is 0.004%, which this Court finds is acceptably a 'very small' risk of identification pursuant to 45 C.F.R. § 164.514." The record is devoid of

[5] The parties did not request oral argument.

any expert supporting the assertion that it was proper to substitute the entire Medicaid patient population in a formula designed to match Medicaid patients in hospice whose last date of service matched the date of death in the Death Database.

The trial court granted Janssen's motion and followed its recommendations to further mitigate risk of re-identification. The court ruled:

- The State is ordered to produce the Medicaid claims data with full dates of service and dispensing, but without birth year, gender, marital status, and race/ethnicity variables.
- The Defendants are prohibited from making any effort whatsoever to take this data or any other data and link it up to any named data, permitting re-identification.
- The distribution of this data would be strictly restricted to Defendants' counsel and Defendants' expert and the fewest number of people from his office needed to assist him with the data analysis. The newly produced data will be maintained otherwise subject to the Protective Order entered in this matter.
- The Defendants are required to contemporaneously destroy, and certify the destruction of, the prior Medicaid dataset produced by the State and provided to the Defendants' expert, prior to the provision of this data.
- The Defendants are prohibited from providing the DOH mortality data set or any other "naming data source" to the expert who will conduct this analysis.
- Defendants will pay for additional redaction and costs incurred as a result of providing this data.

The trial court denied the State's motion for reconsideration. The State filed a notice of discretionary review to this court. Interlocutory review under RAP 2.3(b)(2) requires a showing of "probable error" in a trial court decision that "substantially alters the status quo or substantially limits the freedom of a party to act." Review may be granted where the superior court has departed from the usual course of judicial proceedings. RAP 2.3(b)(3). A commissioner of this court granted discretionary review.

DISCUSSION

Standard of Review

It is within the trial court's discretion to deny a motion to compel discovery and we will not disrupt the ruling absent an abuse of discretion. Clarke v. State Att'y Gen.'s Off., 133 Wn. App. 767, 777, 138 P.3d 144 (2006) (citing Shields v. Morgan Fin., Inc., 130 Wn. App. 750, 759, 125 P.3d 164 (2005)). "A trial court abuses its discretion if its decision is manifestly unreasonable or based on untenable grounds or untenable reasons." Marriage of Littlefield, 133 Wn.2d 39, 46-47, 940 P.2d 1362 (1997).

Timeliness

As a threshold matter, Janssen contends that the State failed to timely file a notice for discretionary review, time barring review. Janssen claims that the State was required under RAP 5.2(b)(1) to file a notice for discretionary review within 30 days after the entry of the order granting Janssen's motion to compel, on which the State seeks review here. Respondent argues that review is time-barred because the State only filed its notice for discretionary review 30 days after the trial court's entry of the order denying the State's motion for reconsideration of the order to which the State assigns error. Janssen asserts the State is limited to review of the denial of its motion for reconsideration, not the underlying order.

A timely motion for reconsideration will extend the 30-day deadline to appeal the original order. Singleton v. Naegeli Reporting Corp., 142 Wn. App. 598, 603, 175 P.3d 594 (2008). Under CR 59, an aggrieved party may move for reconsideration of a decision or order "not later than 10 days" after the entry of the order or decision. CR 59(b). Here, the trial court entered its order on April 13, 2022 sustaining Janssen's

objection to the special master's ruling and order denying its request for the State to produce the Medicaid claims database with supplemental data fields. The State moved for reconsideration on April 29, 2022, outside the 10-day limit permitted under CR 59(b).

In its response to the State's motion for discretionary review, Janssen argued that the State's notice for discretionary review was barred under RAP 5.2(b) as untimely because it was filed more than 30 days after entry of the trial court's decision. The commissioner of this court did not address the issue of timeliness in its Ruling Granting Discretionary Review. Janssen did not move to modify the order.

Consideration of a motion for discretionary review is governed by the regular motion procedure, RAP 6.2(c), requiring an aggrieved party to object to a ruling only by way of a motion to modify. RAP 17.7(a). See City of Spokane v. Marquette, 103 Wn. App. 792, 797, 14 P.3d 832 (2000), rev'd on other grounds, 146 Wn.2d 124, 43 P.3d 502 (2002). Because Janssen did not move to modify the commissioner's ruling, it has waived any argument that the granting of discretionary review was improper because the request was untimely.

Expert Determination

The State contends that the trial court erred in ordering it to produce the supplemental Medicaid claims data to include the day and month in the date of service field, rather than just the year. The State argues that Janssen's expert failed to comply with the requirements of the Expert Determination method of producing HIPAA protected information. We agree.

The parties agree that 45 C.F.R. § 164.514(b)(1) provides the requirements for the Expert Determination method. Releasing the full dates in the Medicaid Dataset is

contrary to 45 C.F.R. § 164.514(b)(2)(i)(C) under the Safe Harbor method. Thus, for the court to be satisfied that the release of full dates would not create a "reasonable basis to believe that the information can be used to identify an individual," 45 C.F.R. § 164.514(a), a qualified expert, applying principles and methods for rendering information not individually identifiable, had to document the methods and results of its analysis that determined the "the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information." 45 C.F.R. § 164.514(b)(1)(i) and (ii).

It appears the trial court misread the record. First, it incorrectly found that the State and the Special Master applied an incorrect risk level of "any risk" instead of the correct standard of a "very small risk" under 45 C.F.R. § 164.514(b)(1)(i). The State submitted Dr. Sweeney's declaration where she acknowledged that HIPAA does not require the risk to be zero before health data may be shared. The Special Master expressly found that Janssen did not meet its burden of showing the "risk is very small" under §164.514(b).

Second, the trial court incorrectly attributed to Dr. Marais an analysis and formula that he did not make or suggest. Nowhere does Dr. Marais propose replacing the denominator of Medicaid hospice patients in Dr. Sweeney's analysis with the entire number of Medicaid patients in the Dataset. That suggestion instead came from the Janssen attorneys in their brief.

Janssen argues that "Dr. Marais considered all of the 'data sets produced in this proceeding' and publicly available dataset." First, Dr. Marais made no such claim. His

declaration reveals that he did not review or consider the consequences of the Death Dataset before opining that the risk was "nil." He based his opinion on the "simple fact" that Janssen does not have "another, complementary data source that could reveal the identifies of individual patients" that could be compared to the Medicaid claims database to provide identifying information. It is undisputed that the Death Dataset included identifiable information, including names. Dr. Marais did not document having applied principles and methods for rendering information not individually identifiable. Dr. Marais' declaration simply states "Based on my education, pertinent experience, and pertinent background knowledge, it is my opinion that the re-identification risk associated with the production Janssen seeks, whether arising from the completed dates alone or in combination with other demographic information produced to date, or with other publicly accessible information, is *de minimis*."

The trial court adopted the suggestion by Janssen's attorneys that Dr. Sweeney's analysis should be changed to replace the denominator in her risk assessment formula from the total number of hospice patients in the Medicaid Dataset to the entire 4.5 million people in the Dataset in order to get to a lower risk percentage. This is without any support from any expert that doing so is a proper measurement of calculating the risk of re-identifying the subset of hospice patients in the Medicaid Dataset.

In contrast, Dr. Sweeney provided detailed explanations of the generally accepted method she applied in making her determinations regarding the risk of re-identification. Dr. Sweeney also demonstrated how the ability to identify unique individuals increased as more datapoints were included in the analysis. She also applied the methods in five separate applications and considered how the additional

information requested could be compared with datasets previously provided to Janssen in discovery and how such information is publicly available.

It appears the trial court also reasoned that changing Dr. Sweeney's analysis was appropriate because there was no justification to looking at only hospice patients. The trial court appeared to misunderstand why Dr. Sweeney focused on hospice patients. The concern under HIPAA is whether there is a "reasonable basis to believe that the information *can* be used to identify *an individual*." 45 C.F.R. § 164.514(a) (emphasis added). The question is whether "the risk is very small that the information *could be used* . . . *to identify an individual* who is a subject of the information." 45 C.F.R. § 164.514(b)(1)(i) (emphasis added). That is a different question than whether the percentage of identifiable people out of the total number of people whose records are released is very small. OCR's guidance notes that "experts are advised to consider how data sources that are available to a recipient of health information . . . *could be utilized* for identification of *an individual*." (Emphasis added.) Dr. Sweeney demonstrated through her analysis that, even before using full dates, the data sources *could* be used to identify 191 unique individuals. Janssen cites to no authority that suggests an analysis under the Expert Determination method must calculate the risk of identifying the entire population within the data set.

Regardless, the trial court could not substitute its opinion or the opinion of the Janssen attorneys for that of a qualified expert under 45 C.F.R. § 165.514(b)(1)(i) and (ii). Because the record establishes that Dr. Marais' expert opinion did not satisfy 45 C.F.R. § 165.514(b)(1)(i) and (ii), we hold that the trial court's reliance on Dr. Marais' opinion was untenable and that the court abused its discretion in determining that the

Expert Determination method was satisfied under HIPAA as a basis to grant Janssen's motion to compel HCA, a covered entity, to disclose full dates in the Medicaid claims database.

Release Under Court Order

While HIPAA controls what a "covered entity" may release, it does allow disclosure of protected health information in the course of a judicial proceeding if certain requirements are met. 45 C.F.R. § 164.512(e)(1). Disclosures are permitted in "response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order" and that a "qualified protective order means" one that

> (A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and
>
> (B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

45 C.F.R. § 164.512(e)(1)(v). However, the parties do not dispute that because the Medicaid Dataset includes substance use disorder patient records, 42 C.F.R. part 2 also applies to the requested records.

Records identifying any patient receiving treatment or rehabilitation for a substance use disorder under a federally conducted or funded program, such as Medicaid, are required to be "confidential". 42 U.S.C. § 290dd-2(a); See Daybreak Youth Servs. v. Clark County Sheriff's Off., 19 Wn. App. 2d 879, 892, 498 P.3d 571 (2021). Disclosure is only permitted through means expressly authorized under 42 U.S.C. § 290dd-2. The statute generally requires patient consent to disclose the

records, but makes express exceptions for disclosure in limited circumstances. 42 U.S.C. § 290dd-2(b)(2)(A)-(D). One such exception is permitted "if authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor." 42 U.S.C. § 290dd-2(b)(2)(C); Daybreak Youth Servs., 19 Wn. App. 2d at 889. A court granting such an order must "weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services" in assessing good cause. 42 U.S.C. § 290dd-2(b)(2)(C). Federal regulations further explain the process for disclosure of identifying information.

The restrictions under 42 U.S.C. § 290dd-2 apply to any records which "would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person." 42 C.F.R. § 2.12(a)(i).

Janssen does not attempt to argue that the trial court weighed the public interest and need for disclosure or assessed good cause. Instead, Janssen contends the information requested is de-identified so neither HIPAA nor part 2 prohibits disclosure.[6] The trial court imposed "conditions in compliance with 42 C.F.R. § 2.11" as part of its order to compel. In addition to HIPAA concerns, a commissioner of this court granted discretionary review to consider whether the trial court committed error by ordering release of protected health information which could be further used to identify

[6] Janssen also contends that the parties had entered into a qualifying protective order that satisfies HIPAA for patients who did not have a substance use disorder. We granted Janssen's request to supplement the record with a copy of this protective order, but this order was entered prior to Janssen's motion to compel disclosure of the full service and prescription dates and the trial court did not rule on whether the HIPAA-compliant Protective Order previously entered by the court overrides the application of the Safe Harbor provision. That issue is not before us.

substance-use disorder patients in violation of 42 U.S.C. § 290dd-2(b)(1) and (b)(2)(C), and implementing regulations at 42 C.F.R. §§ 2.1-2.67.

As the trial court recognized, 42 C.F.R. § 2.11 defines patient identifying information to include "information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information."

"42 C.F.R. § 2.61 defines the legal effect of a court order entered under the regulations. The order's 'only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited.'" Daybreak Youth Servs., 19 Wn. App. 2d at 889 (quoting 42 C.F.R. § 2.61(a)).

If the court decides to issue an order authorizing disclosure, the court must determine that good cause for the disclosure exists. 42 C.F.R. § 2.64(d). To find good cause, the court must determine that

> (1) Other ways of obtaining the information are not available or would not be effective; and
>
> (2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

42 C.F.R. § 2.64(d). Prior to an order authorizing disclosure, both the patient and the record holder must be provided with

> (1) Adequate notice in a manner which does not disclose patient identifying information to other persons; and
>
> (2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order as described in § 2.64(d).

42 C.F.R. § 2.64(b).

In addition to the required findings and notice, the order itself must:

(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

42 C.F.R. § 2.64(e).[7]

Because the trial court ruled that Janssen's expert satisfied the Expert Determination method,[8] the court presumably believed the requested information under the motion to compel was not individually identifiable health information as defined in 42 C.F.R. § 2.11. Because we conclude this record does not support the trial court's determination that the Expert Determination was satisfied, in order for the trial court to order release of any identifiable health information otherwise protected under 42 C.F.R. part 2, the trial court was required to find good cause under 42 C.F.R. § 2.64(d) and require notice be provided under 42 C.F.R. § 2.64(b) before ordering disclosure and imposing limitations and conditions under 42 C.F.R. § 2.64(e). It is undisputed that the

[7] The court order alone does not compel disclosure, but must be accompanied by "a subpoena or a similar legal mandate" in order to compel the disclosure. 42 C.F.R. § 2.61(a).

[8] Though the trial court adopted Dr. Marias' suggestion to grant Janssen's request for full dates in the Medicaid Dataset while limiting other data points, the record is absent of any Expert Determination analysis as to whether release of such a combination of data satisfies HIPAA.

court did not grant the motion to compel under 42 C.F.R. § 2.64.

Accordingly, we reverse.

Coburn, J.

WE CONCUR:

Bilke, J.

Smith, C.J.

FILED
9/18/2023
Court of Appeals
Division I
State of Washington

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION ONE

STATE OF WASHINGTON, Appellant, v. JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; and XYZ Corporations 1 through 20, Respondents.	No. 84140-8-I ORDER GRANTING MOTION TO PUBLISH

The appellant, State of Washington, having filed a motion to publish opinion, and the panel having considered the motion, and finding that the opinion dated July 31, 2023 will be of precedential value; now, therefore it is hereby

ORDERED that the unpublished opinion filed July 31, 2023 shall be published.

FOR THE COURT:

Colum, J.

KeyCite Yellow Flag - Negative Treatment
Proposed Regulation

Code of Federal Regulations
Title 42. Public Health
Chapter I. Public Health Service, Department of Health and Human Services (Refs & Annos)
Subchapter A. General Provisions
Part 2. Confidentiality of Substance Use Disorder Patient Records (Refs & Annos)
Subpart B. General Provisions

42 C.F.R. § 2.11

§ 2.11 Definitions.

Effective: August 14, 2020
Currentness

For purposes of the regulations in this part:

Central registry means an organization which obtains from two or more member programs patient identifying information about individuals applying for withdrawal management or maintenance treatment for the purpose of avoiding an individual's concurrent enrollment in more than one treatment program.

Diagnosis means any reference to an individual's substance use disorder or to a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment.

Disclose means to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person.

Federally assisted—see § 2.12(b).

Informant means an individual:

(1) Who is a patient or employee of a part 2 program or who becomes a patient or employee of a part 2 program at the request of a law enforcement agency or official; and

(2) Who at the request of a law enforcement agency or official observes one or more patients or employees of the part 2 program for the purpose of reporting the information obtained to the law enforcement agency or official.

Maintenance treatment means long-term pharmacotherapy for individuals with substance use disorders that reduces the pathological pursuit of reward and/or relief and supports remission of substance use disorder-related symptoms.

Member program means a withdrawal management or maintenance treatment program which reports patient identifying information to a central registry and which is in the same state as that central registry or is in a state that participates in data sharing with the central registry of the program in question.

Minor, as used in the regulations in this part, means an individual who has not attained the age of majority specified in the applicable state law, or if no age of majority is specified in the applicable state law, the age of 18 years.

Part 2 program means a federally assisted program (federally assisted as defined in § 2.12(b) and program as defined in this section). See § 2.12(e)(1) for examples.

Part 2 program director means:

(1) In the case of a part 2 program that is an individual, that individual.

(2) In the case of a part 2 program that is an entity, the individual designated as director or managing director, or individual otherwise vested with authority to act as chief executive officer of the part 2 program.

Patient means any individual who has applied for or been given diagnosis, treatment, or referral for treatment for a substance use disorder at a part 2 program. Patient includes any individual who, after arrest on a criminal charge, is identified as an individual with a substance use disorder in order to determine that individual's eligibility to participate in a part 2 program. This definition includes both current and former patients.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information. The term does not include a number assigned to a patient by a part 2 program, for internal use only by the part 2 program, if that number does not consist of or contain numbers (such as a social security, or driver's license number) that could be used to identify a patient with reasonable accuracy from sources external to the part 2 program.

Person means an individual, partnership, corporation, federal, state or local government agency, or any other legal entity, (also referred to as “individual or entity”).

Program means:

(1) An individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

(2) An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

(3) Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

Qualified service organization means an individual or entity who:

(1) Provides services to a part 2 program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(2) Has entered into a written agreement with a part 2 program under which that individual or entity:

(i) Acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the part 2 program, it is fully bound by the regulations in this part; and

(ii) If necessary, will resist in judicial proceedings any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by the regulations in this part.

Records means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts), provided, however, that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not become a record subject to this Part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider. Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as records in the hands of the non-part 2 provider, but may be segregated by that provider. For the purpose of the regulations in this part, records include both paper and electronic records.

Substance use disorder means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For the purposes of the regulations in this part, this definition does not include tobacco or caffeine use.

Third-party payer means an individual or entity who pays and/or agrees to pay for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of the patient's family or on the basis of the patient's eligibility for federal, state, or local governmental benefits.

Treating provider relationship means that, regardless of whether there has been an actual in-person encounter:

(1) A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual or entity, and;

(2) The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.

Treatment means the care of a patient suffering from a substance use disorder, a condition which is identified as having been caused by the substance use disorder, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means any federal, state, or local law enforcement agency or official who enrolls in or becomes an employee of a part 2 program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

Withdrawal management means the use of pharmacotherapies to treat or attenuate the problematic signs and symptoms arising when heavy and/or prolonged substance use is reduced or discontinued.

Credits

[85 FR 43036, July 15, 2020]

SOURCE: 82 FR 6115, Jan. 18, 2017; 82 FR 10863, Feb. 16, 2017, unless otherwise noted.

AUTHORITY: 42 U.S.C. 290dd–2.

Current with amendments received through October 15, 2023. Some rules may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Regulation

Code of Federal Regulations
Title 42. Public Health
Chapter I. Public Health Service, Department of Health and Human Services (Refs & Annos)
Subchapter A. General Provisions
Part 2. Confidentiality of Substance Use Disorder Patient Records (Refs & Annos)
Subpart B. General Provisions

42 C.F.R. § 2.12

§ 2.12 Applicability.

Effective: August 14, 2020
Currentness

(a) General—

(1) Restrictions on disclosure. The restrictions on disclosure in the regulations in this part apply to any records which:

(i) Would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person; and

(ii) Contain drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972 (part 2 program), or contain alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment.

(2) Restriction on use. The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290dd–2(c)) applies to any information, whether or not recorded, which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972 (part 2 program), or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for the treatment, or making a referral for the treatment.

(b) Federal assistance. A program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (2) of this section relating to the Department of Veterans Affairs and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Participating provider in the Medicare program;

(ii) Authorization to conduct maintenance treatment or withdrawal management; or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of federal financial assistance in any form, including financial assistance which does not directly pay for the substance use disorder diagnosis, treatment, or referral for treatment; or

(ii) Conducted by a state or local government unit which, through general or special revenue sharing or other forms of assistance, receives federal funds which could be (but are not necessarily) spent for the substance use disorder program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) Exceptions—

(1) Department of Veterans Affairs. These regulations do not apply to information on substance use disorder patients maintained in connection with the Department of Veterans Affairs' provision of hospital care, nursing home care, domiciliary care, and medical services under Title 38, U.S.C. Those records are governed by 38 U.S.C. 7332 and regulations issued under that authority by the Secretary of Veterans Affairs.

(2) Armed Forces. The regulations in this part apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and those components of the Department of Veterans Affairs furnishing health care to veterans.

(3) Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program. The restrictions on disclosure in the regulations in this part do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with substance use disorders if the communications are:

(i) Within a part 2 program; or

(ii) Between a part 2 program and an entity that has direct administrative control over the program.

(4) Qualified service organizations. The restrictions on disclosure in the regulations in this part do not apply to communications between a part 2 program and a qualified service organization of information needed by the qualified service organization to provide services to the program.

(5) Crimes on part 2 program premises or against part 2 program personnel. The restrictions on disclosure and use in the regulations in this part do not apply to communications from part 2 program personnel to law enforcement agencies or officials which:

(i) Are directly related to a patient's commission of a crime on the premises of the part 2 program or against part 2 program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) Reports of suspected child abuse and neglect. The restrictions on disclosure and use in the regulations in this part do not apply to the reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities. However, the restrictions continue to apply to the original substance use disorder patient records maintained by the part 2 program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) Applicability to recipients of information—

(1) Restriction on use of information. The restriction on the use of any information subject to the regulations in this part to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a part 2 program, regardless of the status of the person obtaining the information or whether the information was obtained in accordance with the regulations in this part. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see § 2.17) or through patient access (see § 2.23) is subject to the restriction on use.

(2) Restrictions on disclosures—

(i) Third-party payers, administrative entities, and others. The restrictions on disclosure in the regulations in this part apply to:

(A) Third-party payers with regard to records disclosed to them by part 2 programs or under § 2.31(a)(4)(i);

(B) Entities having direct administrative control over part 2 programs with regard to information that is subject to the regulations in this part communicated to them by the part 2 program under paragraph (c)(3) of this section; and

(C) Individuals or entities who receive patient records directly from a part 2 program or other lawful holder of patient identifying information and who are notified of the prohibition on re-disclosure in accordance with § 2.32.

(ii) Notwithstanding paragraph (d)(2)(i)(C) of this section, a non-part 2 treating provider may record information about a substance use disorder (SUD) and its treatment that identifies a patient. This is permitted and does not constitute a record that has been re-disclosed under part 2, provided that any SUD records received from a part 2 program or other lawful holder are segregated or segmented. The act of recording information about a SUD and its treatment does not by itself render a medical record which is created by a non-part 2 treating provider subject to the restrictions of this part 2.

(e) Explanation of applicability—

(1) Coverage. These regulations cover any information (including information on referral and intake) about patients receiving diagnosis, treatment, or referral for treatment for a substance use disorder created by a part 2 program. Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and provide substance use disorder diagnosis, treatment, or referral for treatment. However, the regulations in this part would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of substance use disorder diagnosis, treatment, or referral for treatment and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) Federal assistance to program required. If a patient's substance use disorder diagnosis, treatment, or referral for treatment is not provided by a part 2 program, that patient's record is not covered by the regulations in this part. Thus, it is possible for an individual patient to benefit from federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in paragraph (b) of this section. For example, if a federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by the regulations in this part unless the program itself received federal assistance as defined by paragraph (b) of this section.

(3) Information to which restrictions are applicable. Whether a restriction applies to the use or disclosure of a record affects the type of records which may be disclosed. The restrictions on disclosure apply to any part 2–covered records which would identify a specified patient as having or having had a substance use disorder. The restriction on use of part 2 records to bring criminal charges against a patient for a crime applies to any records obtained by the part 2 program for the purpose of

diagnosis, treatment, or referral for treatment of patients with substance use disorders. (Restrictions on use and disclosure apply to recipients of part 2 records under paragraph (d) of this section.)

(4) How type of diagnosis affects coverage. These regulations cover any record reflecting a diagnosis identifying a patient as having or having had a substance use disorder which is initially prepared by a part 2 provider in connection with the treatment or referral for treatment of a patient with a substance use disorder. A diagnosis prepared by a part 2 provider for the purpose of treatment or referral for treatment, but which is not so used, is covered by the regulations in this part. The following are not covered by the regulations in this part:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement agencies or officials; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved does not have a substance use disorder (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

Credits

[85 FR 43036, July 15, 2020]

SOURCE: 82 FR 6115, Jan. 18, 2017; 82 FR 10863, Feb. 16, 2017, unless otherwise noted.

AUTHORITY: 42 U.S.C. 290dd–2.

Current with amendments received through October 15, 2023. Some rules may be more current, see credits for details.

End of Document

Code of Federal Regulations
Title 45. Public Welfare
Subtitle A. Department of Health and Human Services (Refs & Annos)
Subchapter C. Administrative Data Standards and Related Requirements (Refs & Annos)
Part 164. Security and Privacy (Refs & Annos)
Subpart E. Privacy of Individually Identifiable Health Information (Refs & Annos)

45 C.F.R. § 164.514

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

Effective: June 7, 2013
Currentness

(a) Standard: De-identification of protected health information. Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

(b) Implementation specifications: Requirements for de-identification of protected health information. A covered entity may determine that health information is not individually identifiable health information only if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(c) Implementation specifications: Re-identification. A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

(1) Derivation. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

(2) Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(d)(1) Standard: minimum necessary requirements. In order to comply with § 164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.

(2) Implementation specifications: Minimum necessary uses of protected health information.

(i) A covered entity must identify:

(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and

(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.

(3) Implementation specification: Minimum necessary disclosures of protected health information.

(i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.

(ii) For all other disclosures, a covered entity must:

(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:

(A) Making disclosures to public officials that are permitted under § 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);

(B) The information is requested by another covered entity;

(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or

(D) Documentation or representations that comply with the applicable requirements of § 164.512(i) have been provided by a person requesting the information for research purposes.

(4) Implementation specifications: Minimum necessary requests for protected health information.

(i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.

(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(5) Implementation specification: Other content requirement. For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical

record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

(e)(1) Standard: Limited data set. A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) Implementation specification: Limited data set: A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;

(iv) Fax numbers;

(v) Electronic mail addresses;

(vi) Social security numbers;

(vii) Medical record numbers;

(viii) Health plan beneficiary numbers;

(ix) Account numbers;

(x) Certificate/license numbers;

(xi) Vehicle identifiers and serial numbers, including license plate numbers;

(xii) Device identifiers and serial numbers;

(xiii) Web Universal Resource Locators (URLs);

(xiv) Internet Protocol (IP) address numbers;

(xv) Biometric identifiers, including finger and voice prints; and

(xvi) Full face photographic images and any comparable images.

(3) Implementation specification: Permitted purposes for uses and disclosures.

(i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) Implementation specifications: Data use agreement—

(i) Agreement required. A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) Contents. A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(1) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(2) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(3) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(4) Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(5) Not identify the information or contact the individuals.

(iii) Compliance.

(A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(1) Discontinued disclosure of protected health information to the recipient; and

(2) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

(f) Fundraising communications.

(1) Standard: Uses and disclosures for fundraising. Subject to the conditions of paragraph (f)(2) of this section, a covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of § 164.508:

(i) Demographic information relating to an individual, including name, address, other contact information, age, gender, and date of birth;

(ii) Dates of health care provided to an individual;

(iii) Department of service information;

(iv) Treating physician;

(v) Outcome information; and

(vi) Health insurance status.

(2) Implementation specifications: Fundraising requirements.

(i) A covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by § 164.520(b)(1)(iii)(A) is included in the covered entity's notice of privacy practices.

(ii) With each fundraising communication made to an individual under this paragraph, a covered entity must provide the individual with a clear and conspicuous opportunity to elect not to receive any further fundraising communications. The method for an individual to elect not to receive further fundraising communications may not cause the individual to incur an undue burden or more than a nominal cost.

(iii) A covered entity may not condition treatment or payment on the individual's choice with respect to the receipt of fundraising communications.

(iv) A covered entity may not make fundraising communications to an individual under this paragraph where the individual has elected not to receive such communications under paragraph (f)(2)(ii) of this section.

(v) A covered entity may provide an individual who has elected not to receive further fundraising communications with a method to opt back in to receive such communications.

(g) Standard: Uses and disclosures for underwriting and related purposes. If a health plan receives protected health information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may only use or disclose such protected health information for such purpose or as may be required by law, subject to the prohibition at § 164.502(a)(5)(i) with respect to genetic information included in the protected health information.

(h)(1) Standard: Verification requirements. Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.

(2) Implementation specifications: Verification.

(i) Conditions on disclosures. If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance

is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.

(A) The conditions in § 164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

(B) The documentation required by § 164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with § 164.512(i)(2)(i) and (v).

(ii) Identity of public officials. A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;

(B) If the request is in writing, the request is on the appropriate government letterhead; or

(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

(iii) Authority of public officials. A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;

(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.

(iv) Exercise of professional judgment. The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with § 164.510 or acts on a good faith belief in making a disclosure in accordance with § 164.512(j).

Credits

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002; 78 FR 5700, Jan. 25, 2013; 78 FR 34266, June 7, 2013]

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Current with amendments received through October 15, 2023. Some rules may be more current, see credits for details.

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DECLARATION OF SERVICE

I declare that on this day I electronically filed the foregoing document with the Clerk of the Court via the Washington State Appellate Courts' Portal, which will serve a copy of this document upon all counsel of record.

I declare under the penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

Dated: October 18, 2023, at Seattle, Washington.

s/ Kelly M. Kennedy
Kelly M. Kennedy, Legal Assistant
Morgan, Lewis & Bockius LLP

MORGAN, LEWIS & BOCKIUS LLP

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