STATEMENT

PhRMA
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**In Opposition to Minnesota Senate File 4699**
**Health and Human Services Committee Budget and Policy Omnibus**
**April 2024**

**Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes the following provisions in Minnesota House Senate File 4699 (SF 4699):**

1. **Article 1, Section 4: Requires drug manufacturers to enter into a value-based arrangement (VBA) with the Commissioner of Human Services in order for a hospital to be reimbursed for a biological drug used as part of cell or gene therapy to treat rare disease provided in an inpatient hospital setting.**

2. **Article 6, Section 4: Strikes rulemaking requirements for developing and posting a list of "prescription drugs of substantial public interest."**

**PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.**

## *Mandatory VBAs for Medicaid Reimbursement of Rare Disease Biological Cell and Gene Therapies*

Since 1990, the Medicaid Drug Rebate Program (MDRP) has been extremely effective at providing broad access to medicines for Medicaid members while also reducing Medicaid drug costs for both the federal government and states. Drug manufacturers give Medicaid programs generally the best discounts in the market through a combination of the MDRP statutory rebates and supplemental rebates negotiated with states. For FFY 2021, drug manufacturers rebated $733 million back to Minnesota, which is 53% of total Medicaid spending on drugs in the state.[1]

Additionally, PhRMA supports innovative contracts—also known as value-based arrangements (VBAs) or alternative financing arrangements—for biopharmaceuticals that are **voluntary** arrangements between manufacturers and other entities, such as health plans or states, in which the price or price concession for a prescription medicine is linked to value as determined and agreed to by the contracting entities. These arrangements have the potential to lower costs through voluntary,

[1]Menges Group analysis of FFY2021 CMS Financial Management Reports (FMR) and State Drug Utilization (SDU) data files. Brand/generic expenditure totals net of rebates. Data predominantly derived from CMS FMRs. Brand/generic prescription drug costs derived through tabulations performed by Menges. Pre-rebate expenditures tabulated using FFY2021 CMS SDU data files and CMS brand/generic indicators for each NDC. Statutory rebates and fee-for-service supplemental rebate information obtained from CMS FMRs. MCO supplemental rebates available in FMRs for several states and estimated in remaining states at similar percentages as the published FMR data indicate. Generic rebates assumed to always be at the statutory 13% level – no supplemental rebates assumed. Total brand rebates are therefore derived as the difference between total rebates and the generic statutory rebates. Post-rebate expenditures derived through Menges tabulations using above information.

market-based negotiations between manufacturers and payers—as opposed to government or other centralized value assessments. States can use innovative contracts as a tool to improve access and bring more value to patients and to the health care system. However, PhRMA opposes **mandatory** arrangements as they have the potential to harm patients, may be difficult to administer and run afoul of federal Medicaid laws.

**Article 1, Section 4 Runs Afoul of the Medicaid Drug Rebate Program.**

The Minnesota Medicaid program pays for prescription drugs administered in an inpatient setting, including cell and gene therapies that treat rare diseases, as part of a bundled payment. As these prescription drugs do not meet the definition of a "covered outpatient drug"[2] under the Medicaid Drug Rebate Program (MDRP)[3], Minnesota does not collect MDRP rebates on claims for these drugs.

Article 1, Section 4 appears to change cell and gene therapies that treat rare diseases into covered outpatient drugs by removing the drug from the bundled payment and reimbursing it separately. It appears the bill makes such changes so the cell and gene therapy drug can be considered a covered outpatient drug and subject to a MDRP rebate.

However, if MN wants to treat these cell and gene therapies as covered outpatient drugs the state must also comply with all requirements of the MDRP law. Under the Medicaid rebate statute, drug manufacturers pay rebates on Medicaid utilization of their products in return for state Medicaid programs covering their products, subject only to certain "permissible restrictions"[4] listed in the statute. As CMS has explained:

> [The Medicaid rebate statute] sets forth requirements for covered outpatient drugs, whereby drug manufacturers must pay statutorily-defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.[5]

The rebate statute's legislative history similarly emphasizes that the statute links manufacturer rebate obligations and Medicaid coverage obligations:

> The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require states that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.[6]

[2] 42 USC § 1396r-8(k)(2)
[3] 42 U.S.C. 1396r–8
[4] 42 U.S.C. 1396r–8(d)(1)
[5] 78 Fed. Reg. 4594, 4631 (Jan. 22, 2013) (emphasis added)
[6] H. Rpt. 101-881, 101st Congress, 2d Session (Oct. 16, 1990) (emphasis added).

Congress required states to cover all products of a manufacturer with a Medicaid rebate agreement (with specified exceptions), to ensure beneficiary access to the full range of drugs that are available to private patients. The statute purposely paired the rebate requirements on manufacturers with the coverage requirements on states; it was described by Congressman Henry Waxman, a key sponsor, as a "government-industry compact."[7] The standard Medicaid Rebate Agreement between CMS and each manufacturer that participates in the rebate program also emphasizes this bargain by detailing manufacturers' obligations to calculate and pay rebates, and recognizing that manufacturers must be able to rely on states fulfilling their end of the statutory bargain (and to enlist CMS's assistance if a state does not fulfill its coverage obligations).[8]

**Article 1, Section 4 effectively prohibits or drastically limits drug coverage in the Medicaid programs of biological cell and gene therapies that treat rare diseases by prohibiting hospital reimbursement of these types of drugs that are not part of a VBA, which is not permissible under federal statute.**

**Prohibiting Reimbursement of Medications Reduces Minnesota Medicaid Enrollee Access to Medicines.**

PhRMA has a long-standing interest in promoting Medicaid members' access to quality care and is concerned that Minnesota's proposal to limit payments to hospitals for prescription drugs will reduce and ration access to lifesaving medicines for Minnesotans. Based on the language and structure of the Social Security Act (SSA), the U.S. Department of Health and Human Services (HHS) and the courts agree that "the core objective of the Medicaid Act is to furnish health-care coverage to the needy."[9] Indeed, the U.S. Court of Appeals for the D.C. Circuit confirmed in 2020 that "the principal objective of Medicaid is providing health care coverage."[10] Prohibiting the reimbursement of hospitals for prescription drugs that are not part of a VBA effectively cuts off members' access to medicines and adversely affects their health by permitting the State to cut back on drug coverage. Medicaid patients, compared to those with other types of insurance, have higher rates of complex and chronic health conditions that often require access, without delay, to a broad range of medicines as prescribed by their physicians in order to achieve optimal therapeutic results,[11] thereby amplifying the potential detrimental effects of this proposal.

**Restricting Access Would Exacerbate Existing Health Inequities.**

There have been myriad longstanding and intersecting systemic, social, and structural barriers that have impeded equitable access to medicines. Research clearly shows that social determinants of health impact life-long health care outcomes.[12] Additionally, patients respond differently to treatment because of a number of factors, such as genetics, age, sex,

[7] Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce, H. Hrg. 103-61, 103rd Cong. 453 (1993) (statement of Rep. Waxman).
[8] Medicaid Rebate Agreement § VI(a) ("A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act [establishing a notice and hearing process for CMS to stop or reduce payments to State Medicaid programs that are out of compliance with their State plan obligations]").
[9] See Philbrick v. Azar, 397 F.Supp.3d 11 (D.D.C. 2019); Gresham v. Azar, 363 F. Supp. 3d 165, 176 (D.D.C. 2019) (noting that the HHS Secretary "refers to the provision of medical care to eligible persons as 'Medicaid's core objective.'"); see also SSA § 1901 (describing the purpose of the Medicaid program as enabling states to furnish "medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services," as well as "rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care").
[10] See Gresham v. Azar, 950 F.3d 93, 99 (D.C. Cir. 2020).
[11] MACStats: Medicaid and CHIP Data Book at Exhibit 43, MACPAC (December 2019), https://www.macpac.gov/wp- content/uploads/2015/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf.
[12] Reno R, Warming E, Zaugg C, Marx K, Pies C. Lessons Learned from Implementing a Place-Based, Racial Justice-Centered Approach to Health Equity. Matern Child Health J. 2021 Jan;25(1):66-71.

socioeconomic status, drug-drug interactions, diet, environment, and comorbidities. This means that treatments that are the best option for some individuals are not as effective for others.[13]

In addition, underserved populations are often treated later for many diseases. Therefore, timely access to provider-recommended medicines is central to reversing that trend, improving health outcomes, decreasing avoidable health care utilization and costs,[14] and reducing mortality. There are a number of conditions disproportionately impacting communities of color, including sickle cell disease and metachromatic leukodystrophy in African American and Hispanic populations, and lupus and sarcoidosis across indigenous communities. Patients of color with rare diseases face extraordinary challenges and experience a disproportionate burden in accessing care.

This proposal could have the unintended consequence of widening health disparities at a time when Minnesota residents are still dealing with the continued effect of the COVID-19 pandemic, and previous and possible pandemic-induced health conditions.

**Research Shows the Limiting Access to Prescription Drugs Hurts Patients, Lowers Adherence and Does Not Reduce Health Care Costs.**

Article 1, Section 4 threatens the health of Medicaid members by limiting access to a host of medicines and imposing significant restrictions if a VBA were not in place for certain medicines. Medicaid members are more likely to be in fair or poor health and have complex and chronic health conditions that often require access to a broad range of medicines compared to those with private insurance.[15] If the Minnesota Legislature chooses to enact these provisions, Minnesota Medicaid members will have virtually no other options if these prescription drugs are not part of a VBA arrangement. The direct damage from reduced access is easy to anticipate—and highly concerning—in view of the extensive research documenting the consequences of restricting access to prescription drugs. Importantly, these studies show that access restrictions reduce adherence to prescribed medication regimens, worsen health outcomes, and drive up long-run costs, both to Medicaid and other state and local programs.

Minnesota's proposal to restrict access to medicines may ration care and may deny members access to a diverse range of treatment options that would best suit their health, biology, and preferences. Research has found that allowing patients and doctors a choice of medicines can increase efficacy of treatments, lower incidence of adverse events, and lower the chances of drug interactions.[16,17, 18]

[13] McRae, J., Onukwugha, E. Why the Gap in Evaluating the Social Constructs and the Value of Medicines?. PharmacoEconomics (2021).
[14] Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. Med Care. 2005 Jun;43(6):521-30.
[15] MACStats: Medicaid and CHIP Data Book, MACPAC (December 2019), https://www.macpac.gov/wp- content/uploads/2015/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf.
[16] Joseph A. DiMasi & Laura B. Faden, Competitiveness in Follow-On Drug R&D: A Race or Imitation?, 10 NATURE REVIEWS DRUG DISCOVERY 23 (2011).
[17] Richard M. Turner et al., Parsing Interindividual Drug Variability: An Emerging Role for Systems Pharmacology, 7 WILEY INTERDISCIPLINARY REVIEWS: SYSTEMS BIO. & MED. 221 (2015).
[18] C. Daniel Mullins et al., Persistence, Switching, and Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, and Citalopram, 25 PHARMACOTHERAPY 660 (2005).

*Prescription Drugs of Substantial Public Interest*

**Rulemaking and Guidance are Necessary before the Department of Health Proceeds with Publishing a List of Drugs of Substantial Public Interest.**

Article 6, Section 4 would exempt new prescription drug transparency reporting requirements for "prescription drugs of substantial public interest" the Minnesota Legislature added to the Minnesota Prescription Drug Price Transparency Act (Act) in 2023. In prior testimony in this Committee, the Department of Health characterized this new provision as a "small portion" of the Act, however these new provisions allow the Commissioner to identify up to 500 prescription drugs for transparency reporting. PhRMA would not characterize requiring reporting from drug manufacturers and other supply chain entities for an additional 500 prescription drugs as small. The reasoning Department of Health provided for the exemption from rulemaking was that it was administratively burdensome and would further delay implementation, not that rulemaking was unnecessary. The addition of "prescription drugs of substantial public interest" to the Minnesota Prescription Drug Price Transparency Act was a significant and meaningful change that should be subject to rulemaking in the same manner as the original drug price transparency language.

Additionally, on November 17, 2023, the Department of Health released updated **draft** reporting guidance on prescription drug price transparency for public comment that included new reporting requirements for drugs of substantial reporting interest. PhRMA submitted comments on the draft guidance by the deadline of December 8, 2023 (see attached). Our letter outlines a number of concerns where additional clarification is needed for the Commissioner to develop the list of drugs of substantial public interest. As stated in our letter, PhRMA believes regulations and further guidance are needed to successfully implement the transparency reporting requirements related to drugs of substantial public interest. As of April 17, 2024, this guidance has yet to be finalized. PhRMA urges the Minnesota Legislature to not exempt the Department of Health from rulemaking to ensure that the processes and procedures related to reporting of prescription drugs of substantial public interest are clearly outlined for implementation and compliance.

**PhRMA respectfully opposes the provisions outlined above and appreciates your consideration prior to advancing SF 4699.**

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December 8, 2023

Prescription Drug Price Transparency Program
Minnesota Department of Health
625 Robert St. N.
St. Paul, MN 55164

**Submitted via electronic mail:** health.Rx@state.mn.us

**Re: Minnesota Department of Health Draft Form and Manner for Prescription Drug Data Sets – Updated November 17, 2023**

To Whom it May Concern:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") thanks you for the opportunity to comment on the Minnesota Department of Health's ("MDH's") continued work on implementation of the Prescription Drug Price Transparency Act (2020 Minn. Laws ch. 78, codified as Minn. Stat. § 62J.84; as amended by 2021 Minn. Laws ch. 30, art. 3, §§ 5–9; and as further amended by 2023 S.F. 2995, Minn. Laws ch. 70, art.2 §§ 8 to 21, 43) (the "Act"). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. In Minnesota alone, there are 25 facilities involved in the manufacturing of medicines and more than 61,000 jobs are supported by the biopharmaceutical sector.

Our comments below are focused on the recently issued draft Form and Manner for Prescription Drug Price Data Sets, updated November 17, 2023 (the "draft Form and Manner" document, or "Draft")), including but not limited to MDH's updated draft provisions related to selection of and reporting on prescription drugs of substantial public interest.[1]

## I. Prescription Drugs of Substantial Public Interest Reporting

### A. Lack of Clear Standards and Procedures

PhRMA is concerned with the lack of clear standards and procedures in the draft Form and Manner

[1] In filing this comment letter requesting changes to the draft Form and Manner Document, PhRMA reserves all rights to legal arguments with respect to the Minnesota Prescription Drug Price Transparency Act. PhRMA also reiterates and reserves its prior comments related to implementation of the Act, including comments on prior versions of the draft Form and Manner document. *See* Letter from PhRMA to MDH (Jan. 27, 2022); Letter from PhRMA to MDH (Dec. 8, 2021); Letter from PhRMA to MDH (July 26, 2021).

document for how MDH will determine the list of prescription drugs of "substantial public interest."[2] Reporting entities need clear notice and insight into how MDH intends to determine these drugs in order to protect against arbitrary decision-making and allow reporting entities and other stakeholders to assist MDH in identifying any inadvertent errors or oversights in the list determination process. PhRMA urges MDH to revise the draft Form and Manner document to provide for clear and transparent standards for determining the list of drugs of substantial public interest. Doing so is necessary for consistent and appropriate implementation of the requirements of the Act.

As non-exhaustive examples of the lack of clear standards and procedures, PhRMA specifically highlights the following areas from the draft Form and Manner document:

- Identification of "substantial public interest" drugs: The draft Form and Manner document does not address the specific criteria that MDH will evaluate when determining if a drug is of "substantial public interest." Rather, MDH's draft Form and Manner document repeats the statutory language regarding the criteria for selection without providing further detail about how these statutory criteria will be compiled, analyzed, or compared for different drugs. MDH's approach to implementing reporting requirements for drugs of "substantial public interest" should be based on a consistent and clear methodology so that stakeholders and members of the public can understand both the process involved and MDH's determinations.[3] PhRMA asks that the agency begin this process by first identifying in advance, in regulations, the concrete factors it deems relevant, as described in the Act.[4] Any other approach would risk arbitrary and inconsistent decision-making and deprive reporting entities of fair notice of the criteria and decision-making processes to which they will be subject.

- Public comment process: The draft Form and Manner document requires MDH to consider drug products that are identified by members of the public during a public comment process. However, the draft Form and Manner document does not address how the public comment process will operate or how MDH intends to review and weigh the comments and other information it receives from members of the public. MDH should adopt procedures for reviewing and evaluating the accuracy, relevance, and completeness of the information submitted by the public, and should include procedures permitting manufacturers and other reporting entities to provide a response to information considered by MDH. PhRMA therefore urges MDH to revise the draft Form and Manner document to provide greater clarity on the public comment process and how such information will be factored into the agency's decision-making.

- Drug product families: PhRMA requests that MDH provide greater clarity regarding how it intends to consider different products, particularly those of different manufacturers, that it

[2] Draft Form and Manner document, at 10-16.
[3] *See In re Rev. of 2005 Ann. Automatic Adjustment of Charges for All Elec. and Gas Utilities*, 768 N.W.2d 112, 120 (Minn. 2009) (finding that "an agency must generally conform to its prior norms and decisions or, to the extent that it departs from its prior norms and decisions, the agency must set forth a reasoned analysis for the departure that is not arbitrary and capricious.").
[4] Minn. Stat. § 62J.84, subd. 10(a).

determines are in the same "drug product families."[5] As currently set forth in the draft Form and Manner document, the requirement may burden manufacturers with significant reporting requirements based on the pricing or other decisions of another manufacturer whose product may be grouped in the same "drug product family." The disconnection between factors in a manufacturer's control and whether or not their drug becomes subject to the Act's reporting requirements deprives the manufacturer of notice that they may become subject to the Act's obligations. Given that manufacturers may be impacted by decisions or other factors outside of their control, we urge MDH to revise implementation of this requirement in a way that gives manufacturers clear notice when their drugs would be deemed to be of substantial public interest based on their inclusion in a "drug product family".

- Introduction to market: In several places, the draft Form and Manner document requires manufacturers to report information related to a drug's "introduction to market," including the year of a drug's introduction to market.[6] It is unclear whether this term refers to the date of first sale or another date. We ask that MDH confirm that the date of a drug's "introduction to market" refers to the date it is first made available for sale.

- Average claims paid amount: MDH should clarify how it will identify drugs "for which average claims paid amounts exceed 125 percent of the Price as of the claim incurred date . . ."[7] It is unclear which claims data will be used to determine this factor and how this calculation will be performed. Greater clarity with respect to this element will enable manufacturers and other stakeholders to better understand which drugs are likely to be considered based on this factor.

- Acquisition price: MDH should clarify what is meant by "acquisition price," which is a separate reporting element from the "price at acquisition."[8]

We thank MDH for its willingness to collaborate and engage with stakeholders on this implementation process, but the lack of clear standards in the draft Form and Manner document makes it challenging to provide full and meaningful comment, specifically with respect to how MDH intends to evaluate whether a drug is of substantial public interest. PhRMA therefore urges MDH to revise the draft Form and Manner document to provide a clear standard for what constitutes "substantial public interest" and to provide more meaningful guidance regarding how MDH intends to render determinations regarding substantial public interest in a principled, consistent, and reasonable manner that avoids arbitrary distinctions between similarly situated products.

### B. Reporting of International Pricing Information

PhRMA also has concerns with the requirement for manufacturers of brand name drugs of substantial public interest or subject to price growth reporting to report the "ten countries, other than the United

[5] Draft Form and Manner document, at 10.
[6] *Id.* at 10, 34.
[7] *Id.* at 10.
[8] *Id.* at 10, 36.

States, that charged the highest single price" for the drug during the previous calendar year.[9] As described in the draft Form and Manner document, manufacturers would have to report such pricing information based on the "wholesale acquisition cost (WAC) equivalent" in each of the ten countries.[10]

PhRMA is concerned that manufacturers may not have this information or may be legally prohibited from disclosing it. International pricing information is often subject to significant confidentiality requirements and may be confidential by law. For example, manufacturer agreements with sovereign entities like England include strict requirements of confidentiality. Moreover, manufacturers may not possess such information, and such information is unlikely to be tracked based on a WAC equivalent standard. We urge MDH to recognize the legal and practical barriers implicated by this reporting requirement. To address these challenges, we ask that MDH provide flexibility in the draft Form and Manner document where reporting may not be possible or may not be legally permitted, and remove the requirement that international pricing information be based on a WAC equivalent standard.

PhRMA also remains concerned that international pricing information is an inappropriate reference point for policy decisions. The prices set by other countries are influenced by a variety of country-specific factors such as populations, preferences, economic conditions, and cultural norms that may differ markedly from those in the U.S. What is more, using international pricing as a reference ignores the reality that, in many countries, governments are the primary (or only) payer of health care and force companies to accept prices or face restrictions on coverage. Some countries have discriminatory policies or even threaten to break patents on valuable new medicines to force artificially low prices. These regressive and sometimes illegal policies delay patient access to new medicines. The international prices manufacturers would be required to submit under the draft Form and Manner document therefore reflect the harmful and even illegal practices used in other countries to set prices and that ultimately harm market-based competition. This competition is needed to expand patient access, improve affordability, and encourage investment in new treatments and cures.[11]

## II. Confidential and Trade Secret Information

PhRMA has serious concerns about the lack of sufficient protections for sensitive information in the draft Form and Manner document. The document does not implement adequate safeguards for manufacturers' confidential, proprietary, and trade secret information, which it refers to as "Not Public Data or Trade Secret" information ("NPTS"). The absence of sufficient protections, which conflicts with the Act itself, threatens the unlawful and unconstitutional disclosure of such information.

[9] Minn. Stat. § 62J.84, subd. 11(b)(14).
[10] *Id.* at 12.
[11] Research shows that patients in the United States enjoy earlier and less restrictive access to new therapies relative to other countries—whereas access restrictions in many other countries have led to lower survival rates for many of the world's deadliest diseases. *See*, e.g., IQVIA Institute, *Global Oncology Trends 2017, Advances, Complexity and Cost* (May 2017); *see* also Allemani C, Weir HK, et al., *Global Surveillance of Cancer Survival 1995–2009: Analysis of Individual Data for 25,676,887 Patients from 279 Population-based Registries in 67 countries (CONCORD-2)*, Lancet (2015), available athttps://www.ncbi.nlm.nih.gov/pubmed/25467588.

MDH has a statutory obligation not to publish any information considered trade secret information under Minnesota law or under federal law.[12] In addition, the Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets.[13] Courts have thus made clear that "when disclosure [of trade secret information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality . . . can amount to an unconstitutional 'taking' of property."[14]

Consistent with this confidentiality requirement, the Act forbids the Minnesota Department of Health (MDH), as well as its commissioners and contractors, from posting "any information . . . if the information is not public data"; "is trade secret information under" Minnesota law;[15] "or is trade secret information pursuant to the Defend Trade Secrets Act of 2016."[16] The Draft, however, falls short of ensuring that that all such confidential, proprietary, and trade secret information will be protected and kept confidential, as the Act requires.

First, the Draft improperly places the onus of identifying NPTS solely on the reporting entity.[17] Reporting entities, which include "any manufacturer, pharmacy, pharmacy benefit manager, wholesale drug distributor, or any other entity required to submit data under this section,"[18] may not be aware whether they are in possession of NPTS that was generated by or pertains to another entity. For instance, a third-party reporting entity may not be aware of the trade secret owner's efforts to maintain secrecy, the economic value of the secrecy, or the fact that the information is not publicly available. For that reason, the submitter may not be aware that it is submitting trade secret information and may accordingly fail to identify the information as such. This dynamic is particularly problematic because, in situations where one entity submits information obtained from another entity, the third-party may receive no notice of the submission. In order to protect such third-party information from improper disclosure in violation of statutory and constitutional requirements, MDH must proactively evaluate all submissions to identify sensitive information that must be protected—an inquiry that is also required by Act's explicit instruction that MDH may not post "any information" that is confidential, proprietary, or trade secret information.[19]

In addition, the Draft guidance improperly limits the type of information that can be marked as NPTS.[20] PhRMA appreciates that the Draft creates a mechanism for reporting entities to self-identify NPTS by submitting a written statement. But that mechanism does not contemplate that reporting entities will identify all NPTS in their possession. Specifically, to designate information as a trade secret, the Draft requires that the "the Reporting Entity supplying the claimed Trade Secret data is the owner of the data."[21] But as just noted, reporting entities may be in possession of NPTS that

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[12] *See* 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act); Minnesota Uniform Trade Secrets Act, Minn. Stat. § 325C.
[13] *See, e.g., Ruckelshaus v. Monsanto Co*., 467 U.S. 986, 1002–04 (1984). The Fifth Amendment's Taking Clause applies against the states under the Fourteenth Amendment.
[14] *St. Michael's Convalescent Hosp. v. California*, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted)
[15] Minn. Stat. § 13.37, subd. 1(b).
[16] Minn. Stat. § 62J.84, subd. 6(a)(2)(c).
[17] Draft Form and Manner document, at 16.
[18] *Id.* at 5.
[19] Minn. Stat. § 13.37, subd. 1(b) (emphasis added).
[20] Draft Form and Manner document, at 16.
[21] *Id.* at 17.

belongs to a third-party. As written, the Draft makes it impossible for a reporting entity to identify confidential information belonging to a third-party. Similarly, the Draft requires a reporting entity to inform MDH of "efforts to maintain the secrecy of the data."[22] But if the reporting entity is not the owner of the NPTS, then it may not be aware of the efforts made by the NPTS's owner to maintain the information's confidentiality.

These deficient protections for third-party information are particularly egregious because the Draft guidance itself acknowledges that NPTS may be "[s]hared" without losing its status as NPTS, so long as it is shared in a manner that "reasonably ensure[s] secrecy from those who could obtain economic value from the data."[23] The Draft also incorporates the definition of "trade secret" under the Defend Trade Secrets Act, which has no personal-ownership requirement.[24] Despite these acknowledgments of the existence of NPTS obtained from a third-party, the draft Form and Manner document ignores the possibility that a reporting entity may submit the confidential information of a third-party.

The Draft also provides inadequate pre-disclosure procedures to safeguard statutory and constitutional rights. PhRMA recognizes that MDH provides a 30-day process for the review of information designated as NPTS, including the opportunity to challenge an adverse decision under the Minnesota Government Data Practices Act ("MGDPA").[25] Some of these review procedures, however, are insufficient. Under the Draft, when MDH disagrees with a Reporting Entity's designation, MDH "must provide the Reporting Entity written notice that the data will be publicly posted 30 days after receipt of the notice."[26] As discussed above, however, the Reporting Entity may not be the owner of the particular NPTS in dispute. The Draft should therefore be revised to require MDH to notify the owner of the NPTS as well. Along similar lines, the Draft should be revised to acknowledge that challenges to MDH's decision under the MGDPA may be brought not only by the Reporting Entity that submitted the NPTS, but also by the actual owner of the NPTS.

Perhaps most concerning, the Draft provides that "[i]f a Reporting Entity files an MGDPA challenge to an MDH decision to publish data over a Reporting Entity designation, MDH may continue to withhold data that has not been published until the challenge is resolved."[27] To comply with statutory and constitutional protections, MDH has a mandatory duty to protect data that has been designated as NPTS until a challenge to the status of such information is resolved. The Draft accordingly must be revised to state that MDH "must" or "shall" continue to withhold data that has not been published until the challenge is fully resolved. Doing so is also required by constitutional principles. "Once the data that constitute a trade secret are disclosed to others, . . . the holder of the trade secret has lost his property interest in the data," and its value is thereby "destroy[ed]."[28] If MDH were afforded discretion to publish data while its status was still being contested—thus forever "destroy[ing]" the value of the property interest to the entity that generated the information—then the challenge process would become illusory.

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[22] *Id.*
[23] *Id.*
[24] *Id.* at 5.
[25] *Id.* at 18.
[26] *Id.*
[27] *Id.* (emphasis added).
[28] *Ruckelshaus*, 467 U.S. at 1011-12.

Finally, the Draft offers insufficient safeguards to require that all confidential information submitted to MDH will be handled appropriately. The Draft does not indicate how confidential information will be stored or who may access it. Consistent with existing state law governing data protection, MDH should ensure that confidential information is stored in a secure location, accessible only by individuals whose work requires access to the data and only for the period where that access is necessary for the individual's assignment.[29] Any entity with access to information designated as confidential, as well as the employees and contractors of any such entity, should be required to sign non-disclosure agreements making clear that the information is confidential; may only be used to implement the Act and may not be disseminated outside of the group of individuals who are working on the project for which the information is essential and who have signed the nondisclosure agreement. In the event that confidential or trade secret information is shared in a manner inconsistent with these criteria, MDH should alert the manufacturer that owns the information "in the most expedient time possible and without unreasonable delay," as required under state law governing data breaches.[30] The Draft must be updated to identify the steps that MDH will take to protect NPTS against intentional or inadvertent disclosure. As noted above, "failure to provide adequate protection to assure [the] confidentiality" of trade secret information "can amount to an unconstitutional 'taking' of property."

* * *

Thank you for the opportunity to continually engage with MDH regarding the implementation of the Act. We remain committed to discussing these issues with you and working collaboratively toward their resolution. Please do not hesitate to contact Linda Carroll-Shern at lcarroll-shern@phrma.org or Kristina Moorhead at kmoorhead@phrma.org to discuss these items further.

Sincerely,

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[29] *See* Minn. Stat. § 13.05, subd. 5(a)(2).
[30] Minn. Stat. § 13.055, subd. 2(a).