Prescription Drug Price Transparency: Frequently Asked Questions

UPDATED SEPTEMBER 29, 2022

The Frequently Asked Questions document addresses practical approaches to submitting data and speaks to specific circumstances that manufacturers may face. The Minnesota Department of Health (MDH) is posting responses to questions received from public meetings with stakeholders, as well as from more informal inquiries. MDH will update the document as new information emerges and we receive additional questions about implementing the Minnesota Prescription Drug Transparency Act.

Revision History

Date	Version	Description
8/27/2021	1	First draft
12/29/2021	2	Added questions and revised selected responses on items raised through Dec. 2021 that focused on compliance and enforcement
2/23/2022	3	Updates are primarily focused on registration and reporting activities
9/29/2022	4	Added responses to questions raised by reporting entities.

Contents

Program Overview

To increase transparency into the pricing of prescription drugs, the Minnesota Legislature passed the Prescription Drug Price Transparency Act (the "Act") in 2020, which required MDH to develop a system for collecting and reporting data from drug manufacturers on high and quickly increasing prescription drug prices (Minnesota Statutes 62J.84; amended by Minnesota Laws, 2021, Regular Session, Chapter 30 – HF 2128 – Article 3, Sec. 5 - 9).

There are three main components to implementation of the Act:

1. Prescription drug manufacturers report to MDH when drugs meet reporting criteria.
2. MDH publishes reported data that is permitted and required to be published under state law.
3. MDH analyzes the reported data and annually submits a report to the legislature that promotes transparency and supports management of prescription drug spending.

Important Dates

January 1, 2022. Changes to the price of a prescription drug, sales of new acquisitions of prescription drugs, and new listings of a prescription drug for sale in the United States on or after this date may trigger reporting, if all reporting criteria are met. A report can be triggered at any point after this date.

March 2, 2022. The earliest date by which a report may be due to MDH. Data must be submitted by 11:59 p.m. Central Time no later than 60 days after the report is triggered at the time of a price increase, introduction to market of a new drug, or first sale of a newly acquired drug. Thus, if a price change that occurs on January 1, 2022, triggers reporting, the manufacturer's report is due to MDH no later than by 11:59 p.m. Central Time on March 2, 2022.

Who may trigger a required report?

Entities may be required to report under Minnesota's Prescription Drug Transparency Act that:

1. are licensed to operate as prescription drug manufacturers in Minnesota; and
2. set the WAC price for brand name, generic, or biosimilar prescription drugs; and
3. introduced drugs for sale in the United States, recently acquired drugs, or increased the WAC price of drugs on or after January 1, 2022, if the drugs are priced or incur price increases above certain levels.

Entities may review the definitions for these in the Form and Manner guidance document (https://www.health.state.mn.us/data/rxtransparency/docs/rxformmanner022322.pdf) to assess their reporting responsibility.

Communication

How can manufacturers stay updated on implementation of the Act?

MDH will communicate updates and announcements on its website and through emailed GovDelivery bulletins. Manufacturers can monitor website updates on the Announcements page (https://www.health.state.mn.us/data/rxtransparency/announcements.html) and can sign up to receive emailed announcements via GovDelivery bulletins (https://public.govdelivery.com/accounts/MNMDH/subscriber/new?topic_id=MNMDH_553).

What future opportunities will there be for public feedback on implementation of the Act?

MDH is committed to implementing the Act in a transparent way. We provided opportunities for stakeholders to comment on drafts of the Form and Manner guidance throughout 2021 and to provide input on implementation generally. As implementation of the Act continues, MDH welcomes feedback from stakeholders emailed to health.Rx@state.mn.us.

Online Registration and Reporting Portal

I am experiencing issues with the online portal. Where can I find help?

MDH prepared several resources to support reporting entities' use of the online registration and reporting system.

- For reporting guidance, please consult the Form and Manner guidance document (https://www.health.state.mn.us/data/rxtransparency/docs/rxformmanner022322.pdf).
- For practical approaches to submitting data and manufacturer circumstances, please reference this Frequently Asked Questions for Reporting Entities document.
- For guidance on registering and reporting, please review the Online Reporting User Guide (https://www.health.state.mn.us/data/rxtransparency/docs/rxuserguide022322.pdf).
- For a video walkthrough of how to use the reporting system, please view the Minnesota Prescription Drug Price Transparency Reporting Demonstration Video (https://www.youtube.com/watch?v=87_ljXR5c74&feature=youtu.be).
- For any questions not answered by the materials noted above, please email health.Rx@state.mn.us.

Registration

Is registration required?

Registration is required of manufacturers that have a reporting requirement. MDH encourages all manufacturers to register, regardless of their current reporting responsibilities, so as to enable reception of periodic communications.

What does MDH check when reviewing registration requests?

MDH reviews registration requests to confirm that the email domain used to register a manufacturer account is affiliated with a manufacturer licensed in Minnesota. This is to verify the authenticity of the registrant and to make potential registrants aware that reporting is only required of prescription drug manufacturers licensed in Minnesota.

How should a third-party associate intending to report on behalf of a manufacturer register?

Third-party associates should register a "Third Party Associate" account. Once established, an employee of the manufacturer for which the third-party associate will report may then look up the third-party company within the online system and establish an affiliation (after independently registering a contact for their organization using an email domain that matches the manufacturer). This way, multiple manufacturers may delegate reporting to a third-party company, all of which the third-party associate may access and report on behalf of through the Third-Party Associate account while limiting data access to only the third-party associate and the manufacturer.

Reporting

How can manufacturers confirm a report has been successfully submitted to MDH?

Manufacturers submit drug reports to MDH by entering and certifying data in the online portal. Drug reports that have been successfully submitted will appear under the "Ready for Review" tab of the Batch Details page of the online reporting portal. For instructions on how to review the status of a drug report and other functions, MDH prepared a Online Reporting User Guide (https://www.health.state.mn.us/data/rxtransparency/docs/rxuserguide022322.pdf) for reporting entities.

What should a manufacturer do if it is not tracking the information needed for a data element?

Required data are statutorily required; and manufacturers must report the information to the best of their ability. Where necessary, manufacturers may develop estimates and use the General Notes fields to provide context and detail about the methodology used to develop estimates.

Manufacturer Reporting

What entities are subject to the Act?

As noted in the law, entities that are licensed to act as a drug manufacturer in the State of Minnesota under section 151.252 are subject to the Act.

Can another entity report on a manufacturer's behalf?

Yes. The manufacturer may delegate reporting authority to another entity (e.g., subsidiaries, contractors or other third parties) but remains responsible for the accuracy and completeness of any submissions to MDH.

If multiple prescription drug manufacturers have a relationship to a prescription drug that triggers reporting, which entity has the responsibility to report?

By tying the reporting requirement to wholesale acquisition cost (WAC) price, the law places the responsibility for reporting with the entity that sets the WAC price. Other entities may report on a drug on behalf of the responsible manufacturer.

In the following scenarios, we identify which entity has the responsibility to report or have a designee report on their behalf:

Scenario 1. Entity A manufacturers and packages a drug on behalf of Entity B. Entity B controls the price of the drug.

Entity B has the reporting responsibility for Prescription Drug Price Increase reporting (MN Statutes 62J.84, subd. 3) because it controls the price that may trigger reporting.

Scenario 2. Entity A is the parent company to Entity B, which manufactures, packages, and distributes the drug.

If Entity B controls the price of the drug, Entity B has the reporting responsibility associated with any price increases that may trigger reporting (MN Statutes 62J.84, subd. 3). If Entity A controls

the price of the drug, Entity A has the reporting responsibility associated with any price increases that may trigger reporting.

Scenario 3. Entity A increased the price of a drug to a level that triggered required reporting and then sold the drug to Entity B 30-days later, at which point Entity B began selling the drug.

Entity A has the responsibility for the Prescription Drug Price Increase reporting (MN Statutes 62J.84, subd. 3) associated with the price increase that occurred prior to the sale of the drug to Entity B.

Entity B's reporting responsibility depends on whether the drug meets the criteria for reporting on the first day of sale and whether Entity B increased the price to the level that meets the reporting criteria. Possible reporting responsibilities for Entity B are:

- **No reporting responsibility.** If Entity B acquired the drug and the price of the drug does not meet the reporting criteria on the day the acquiring manufacturer begins to sell the drug, Entity B does not have a reporting responsibility related to the drug acquisition. However, future price increases may trigger required reporting for Entity B.
- **Reporting responsibility on acquisition only.** If Entity A was responsible for the full price increase that meets the reporting criteria on the day Entity B begins to sell the drug, Entity B is responsible for reporting only the elements on drug acquisition noted in the Prescription Drug Price Increase reporting (Data elements under items 1 – 7 in the Form and Manner guidance section titled Prescription Drug Price Increase Reporting).
    - For example, assume Entity A increased the price of a drug to amount that meets reporting criteria before selling the drug to Entity B. In this situation, Entity A is responsible for reporting price increase data no later than 60 days after the price increase. Entity B is only responsible for identifying the drug and reporting new acquisition data (Data elements under items 1 – 7 in the Form and Manner guidance section titled Prescription Drug Price Increase Reporting), unless Entity B separately increased the price by an amount that meets price increase reporting criteria on or before the date Entity B began to sell the drug.
- **Reporting responsibility on price increase and acquisition.** If Entity B acquired and increased the price to an amount that meets the reporting criteria on or before the date the acquiring manufacturer begins to sell the drug, Entity B has the responsibility for Prescription Drug Price Increase reporting, including data on the drug acquisition (MN Statutes 62J.84, subds. 3 and 5).
    - **Note:** This responsibility applies even if Entity A was partially responsible for the price increase. To illustrate, Entity A owned a drug and increased the price by an amount that does not meet price increase reporting criteria before selling the drug to Entity B. On or before the date Entity B began to sell the drug, Entity B further increased the price to an amount that meets price increase reporting criteria. If each of Entity A's and Entity B's price increases occurred within the applicable 12- or 24-month reporting window, Entity B is responsible for reporting all price increase and newly acquired drug data. (MN Statutes 62J.84, subds. 3 and 5).

The following table outlines which data elements included in the Prescription Drug Price Increase reporting template are required based on subdivision(s) of Minnesota Statutes 62J.84 under which a manufacturer is required to report:

Data Element	When Required
NDC	Always
Drug Description	
WAC At Introduction	
Year Of Introduction	
WAC Last Day 1 Year Prior	
WAC Last Day 2 Year Prior	
WAC Last Day 3 Year Prior	
WAC Last Day 4 Year Prior	
WAC Last Day 5 Year Prior	
Generic Delay Agreement	
Patent Expiration Date	
WAC at Acquisition	If acquired within 12 months of triggering report
WAC Year Prior to Acquisition	
Company Acquired From	
Date of Acquisition	
Acquisition Price	
WAC Effective Date	If the manufacturer increased the price to trigger a report
WAC After Increase	
Percent Increase Over Previous WAC	
Price Increase Factors	
Generic Nonproprietary Name	
Manufacturing Cost	
Marketing Cost	
Distributing Cost	
Gross Revenue From Sales	
Net Profit	
Financial Assistance Provided	
Manufacturing Company	
Manufacturing Company Address	
Ten Highest Prices Paid for the Drug in Any Country Other than the United States	
General Comments	Optional

Does a manufacturer have to submit data after acquiring an existing drug?

If the acquiring manufacturer increased the price of the drug to an amount that meets the price increase criteria on or before the date the acquiring manufacturer begins to sell the drug, the acquiring manufacturer must report all data required by this section, even if the selling manufacturer was partially responsible for the price increase. However, the acquiring manufacturer is only required to report the data elements specified in data elements under items 1 – 7 in the Form and Manner guidance section titled Prescription Drug Price Increase Reporting if the selling manufacturer was responsible for the full price increase that meets the above criteria.

Please reference Scenario 3 of the previous question on manufacturer relationships.

Is an existing drug with a new labeler code considered a new drug if it is the same drug?

No. Please reference the Form and Manner guidance for the definition of a new prescription drug.

Prescription Drugs

What drugs meet the requirement for reporting under the Act?

Drugs intended for human use subject to United States Code, title 21, section 353(b)(1) are subject to the Act. These drugs require reporting if they meet price increase, new prescription drug, or newly acquired drug criteria. (MN Statutes 62J.84, subd. 3-5).

Can a price increase for a drug prior to January 1, 2022, trigger Prescription Drug Price Increase Reporting?

No. Only price increases that occur on or after January 1, 2022, may trigger Prescription Drug Price Increase Reporting.

Can a drug introduced for sale in the United States prior to January 1, 2022, trigger New Prescription Drug Price Reporting?

No. Only drugs introduced for sale in the United States on or after January 1, 2022, may trigger New Prescription Drug Price Reporting. However, drugs introduced for sale prior to January 1, 2022, may trigger Prescription Drug Price Increase Reporting if they meet the reporting criteria on or after January 1, 2022.

Can a drug that was acquired by a manufacturer that began selling the acquired drug prior to January 1, 2022, trigger reporting of the drug acquisition data element included in the Prescription Drug Price Increase Reporting?

No. Only drugs that the acquiring manufacturer begins to sell on or after January 1, 2022, may trigger the drug acquisition data element (Data elements under items 1 – 7 in the Form and Manner guidance section titled Prescription Drug Price Increase Reporting) included in the Prescription Drug Price Increase Reporting if they meet the reporting criteria. However, drugs acquired and first sold by the manufacturer prior to January 1, 2022, may trigger Prescription Drug Price Increase Reporting if they meet the reporting criteria on or after January 1, 2022.

Can price increases for biosimilars trigger Prescription Drug Price Increase Reporting?

No. Currently, biosimilars only trigger reporting if they meet the triggers for New Prescription Drug Price Reporting when they are first introduced for sale in the United States (MN Statutes 62J.84, subd. 4).

Can the introduction of a new generic drug for sale in the United States that does not have a referenced brand drug on the market trigger New Prescription Drug Price Reporting?

No. Currently, the law does not require reporting under the New Prescription Drug Reporting category for a new generic for which there is no referenced brand name drug for sale in the United States. However, the same generic drug may still trigger Prescription Drug Price Increase Reporting at some later point.

Can orphan or ultra-orphan drugs trigger reporting?

Yes. Orphan and ultra-orphan drugs are subject to the same reporting criteria as other drugs.

Can drugs administered by a physician and drugs delivered in an inpatient setting trigger reporting?

Yes. Drugs administered by a physician and drugs delivered in an inpatient setting are subject to the same reporting criteria as other drugs. Prescription drugs that meet the definition of “a drug for human use subject to United States Code, title 21, section 353(b)(1)” are subject to reporting requirements under the Act; and entities that are licensed to act as a drug manufacturer in the State of Minnesota under section 151.252 are responsible for reporting. Thus, an entity licensed as a manufacturer in the State of Minnesota that sets the WAC price for a physician administered drug that meets the definition of a prescription drug, the entity may be required to report.

What is the minimum price threshold for reporting for new drugs?

One of the criteria for requiring reporting on new prescription drugs is based on the Centers for Medicare and Medicaid Services Specialty Drug tier threshold for Medicare Part D. This amount is $830 as of January 1, 2022;[1] this threshold will change as the Specialty Drug tier threshold is updated in the future.

Manufacturers of a brand drug with a price greater than the Medicare Part D Specialty Drug threshold on the day the manufacturer introduces the drug for sale in the United States must report on that drug.

Manufacturers must report for a generic or biosimilar drug with a price greater than the Medicare Part D Specialty Drug threshold that is not at least 15 percent lower in price than the price of the referenced brand drug on the day the manufacturer introduces the drug for sale in the United States.

Data Definitions and Data Elements

How is the price increase calculated?

To assess reporting responsibility for a given price increase to a drug, a manufacturer should reference the new price increase against the price for that drug 12 and 24 months prior (or the first date of sale, if the drug was introduced for sale less than 12 months prior), as appropriate for the drug, to determine whether the change meets the price increase criteria.

Scenario 1. A price increase to a brand name drug occurs on January 15, 2022.

For price increases involving brand name drugs, the manufacturer must reference the new price against the price for that drug 12 and 24 months prior to determine whether the change meets the price increase criteria (i.e., increases of 10 percent or more over 12 months, or 16 percent or more over 24 months). The new price should be compared against the price of the drug on January 15, 2021, and January 15, 2020.

Scenario 2. A price increase to a generic drug occurs on January 15, 2022.

For price increases involving generic drugs, the manufacturer must reference the new price against the price for that drug 12 months prior to determine whether the change meets price increase criteria (i.e., increases of 50 percent or more over that 12-month period). The new price should be compared against the price of the drug on January 15, 2021.

[1] Centers for Medicare and Medicaid Services. Contract Year 2023 Final Part D Bidding Instructions. February 3, 2022. Available at: https://www.cms.gov/files/document/2023partdbiddinginstructions.pdf.

Scenario 3. A price increase to a prescription drug occurs on January 15, 2022, and the drug was acquired within the last 12 months.

If a manufacturer acquires a drug, the process for calculating a price increase remains the same: the price at which the manufacturer begins to sell the drug should be compared to the price of the drug at the applicable 12- and/or 24-month prior to the price increase. For more information on what information an acquiring manufacturer must report, please reference "Scenario 3" on page 5 – 6 in the answer to the question "If multiple prescription drug manufacturers have a relationship to a prescription drug that triggers reporting, which entity has the responsibility to report?"

What is the "purchase price" of a newly acquired drug?

The "purchase price" is the amount the acquiring manufacturer paid to purchase the drug from another company (MN Statutes 62J.84, subd. 5(b)(2)). It is not the WAC price of the drug at the time of acquisition.

What timeframe can a manufacturer use to report direct cost and financial assistance data elements?

For both report types, the data element should reflect the total amount associated with the specific NDC (not an amount for single unit of the drug).

For Prescription Drug Price Increase Reporting, manufacturers have two options on the time period for the data elements on direct costs to manufacture, market, and distribute the drug, as well as the data element on financial assistance provided to consumers. A manufacturer may report the costs it incurred or the assistance it provided either:

- During the 12-month period preceding the price increase; or
- Cumulatively since the direct cost was first incurred, or the financial assistance was first provided.

Manufacturers must specify the method they choose when reporting direct cost and financial assistance information on the MDH reporting system.

For New Prescription Drug Price Reporting, direct costs to manufacture, market, and distribute the drug should reflect the total amount from the first date manufacturing costs were incurred through the date of introduction to market.

What will MDH do with reported data, including direct cost and financial assistance data?

MDH is required to publicly post all reported information online unless that information meets "trade secret" criteria or is otherwise not public under federal or state law. MDH is also required to synthesize the reported information in an annual report to the Minnesota Legislature. To make

the information more meaningful and comparable, MDH anticipates annualizing some of the reported information. If a manufacturer reports direct costs or financial assistance information for a period other than the 12 months prior to a price increase or acquisition date, MDH anticipates using the reporting information to generate an estimate of annual spending in the reported category.

What costs may a manufacturer include in the reported amounts for direct costs to manufacture, market, and distribute a drug?

Direct costs may include any costs directly attributable on a per-drug basis to the manufacturing, marketing, or distributing of the drug. This may include any labor or third-party vendor costs if they are directly attributable on a per-drug basis.

What types of financial assistance may be included in the total amount provided to patient assistance programs?

A manufacturer may report any form of financial assistance that it provided directly to consumers of the drug, provided the assistance reduced the out-of-pocket cost of the drug to consumers. Examples of financial assistance may include discounts in price or waiver of charges (based on income, need, drug availability, emergency response, or other factors), rebates, or other similar financial assistance provided directly by the manufacturer. Financial assistance does not include benefits to consumers that are not provided directly by the manufacturer, such as government assistance or other benefits that compensate the manufacturer or consumer for the purpose of reducing out-of-pocket costs to consumers.

What date should a manufacturer report if a drug has multiple patents?

Manufacturers should report the date the last patent expires.

Should manufacturers report the chemical name or the name of generic equivalents on the market for the “Generic Nonproprietary Name” data element?

Manufacturers should report the generic or chemical name of the product for which the drug if any generic equivalent is presently available on the market; if the product is not available generically, manufacturers may omit this value.

Should manufacturers report information for the manufacturer providing the report or the contract manufacturer under the

"Manufacturing Company Name" and "Manufacturing Company Address" fields?

For the data fields relating to "Manufacturing Company Name" and "Manufacturing Company Address", reporting entities should enter the manufacturer that physically manufactures the product.

Can manufacturers submit general comments or additional information to explain a price increase, or the price of a new or acquired drug?

In the context of price increases, manufacturers are required to describe and support the factors leading to the price increase. For all reporting, including price increase reporting, manufacturers also have the option to submit additional information and documentation that may explain or relate to the report.

Not Public Data and Trade Secrets

How can a Manufacturer protect "trade secrets" and other not public data reported to MDH?

Not public data and trade secrets (collectively, "not public data") are defined by Minnesota and Federal Law. If a manufacturer believes any of the data it is required to report is not public, the manufacturer must report the data along with a written statement specifically identifying the data and the factual and legal basis for the designation. MDH will not publicly disclose data that a manufacturer demonstrates is not public by a preponderance of evidence (i.e., it is more likely than not that the data is not public).

Please see the Form and Manner guidance, which provides detailed information about the required content of a written statement, the definitions of not public data and trade secrets, and MDH decisions.

If MDH disagrees with a manufacturer's written statement designating data as not public or trade secret, will MDH provide a written statement of its reasoning?

Yes. If MDH disagrees with a manufacturer's written statement, MDH must provide the manufacturer written notice that the data will be publicly posted 30 days after the date of the notice. Within this notice, MDH will provide a written explanation of its decision.

Can a Manufacturer challenge an MDH decision to publicly report data the manufacturer designated as a trade secret or not public?

A manufacturer that would like to challenge an MDH decision to publish data it believes is not public may pursue the administrative or civil remedies available in the Minnesota Government Data Practices Act (MGDPA). Because the Act requires MDH to provide advance notice of 30-days when it disagrees with a manufacturer's written statement, manufacturers have a time-sensitive obligation to pursue a challenge within the notice period and notify MDH. MDH will continue to withhold disputed data until a timely challenge is resolved, unless extraordinary circumstances exist to justify publication.

What will MDH do with the written statements providing the legal basis for withholding data submitted by manufacturers?

MDH is not required to publish manufacturer written statements that identify not public data and, currently, MDH does not intend to do so. As required by the Act, MDH will use the information to explain "the nature of the information and the . . . basis for withholding" any not public data. Minn. Stat. 62J.84, subd. 6(c).

However, MDH does have an obligation to respond to requests for written statements made under the Minnesota Government Data Practices Act (MGDPA). Each MGDPA request is evaluated on a case-by-case basis. In general, MDH must disclose written statements in response to an MGDPA request unless the contents are classified by law as not public. MDH is prohibited from disclosing not public data, except when disclosure is specifically authorized by the MGDPA or other federal and state law.

How will MDH protect not public data and trade secrets?

Data reported to MDH that are classified as not public will be safeguarded by technical and operational protections and the requirements of the Minnesota Government Data Practice Act, the Minnesota IT Services Security Controls (based on the National Institute of Standards and Technology Cybersecurity Framework), and applicable Minnesota IT Services security policies. For more detail on Minnesota IT security policies, please visit: https://mn.gov/mnit/government/policies/security/.

Compliance and Enforcement

What is the maximum penalty a manufacturer may face?

The sum daily total of all penalties across one or more administrative penalty orders issued to a manufacturer for violating the Act may not exceed $10,000.

Will there be a grace period for implementing penalties?

No. The Act does not contemplate a grace period for enforcement and civil penalties. In the months leading up to implementation of the Act, MDH has focused on providing opportunities to gain familiarity with the Act's requirements and to engage in the development of guidance and reporting processes. As a result, MDH is confident that manufacturers are well-prepared to meet the Act's requirements.

How will MDH monitor compliance and communicate with manufacturers about compliance with the Act?

Using reference and other data, MDH will monitor for events that may trigger reporting under the law. Using contact information provided by manufacturers in MDH's registration system, MDH will communicate with manufacturers that may have triggered reporting. Manufacturers may register on the MDH website at https://rxpt.health.mn.gov.

When a manufacturer notifies MDH that it has corrected a violation or developed a corrective plan according to an administrative penalty order, when can the manufacturer expect a response from MDH?

MDH will ordinarily issue written notice of its determination regarding the sufficiency of corrective action within ten working days after receiving the information from the Manufacturer, or within ten working days after the 31st day after MDH issued the penalty order, whichever is later. For more information, see the MDH Plan for the Use of Administrative Penalty Order, Cease and Desist Authority, and Other Enforcement Tools (https://www.health.state.mn.us/communities/environment/local/docs/ehcib/apoplan2010.pdf).

How can a manufacturer challenge an enforcement action by MDH?

A manufacturer may challenge an enforcement action taken by MDH by requesting an expedited administrative hearing. Any administrative penalty order or notice of outstanding corrective action sent to a manufacturer will contain a description of the process for requesting an expedited administrative hearing.