



**PENNSYLVANIA COALITION
FOR INFORMED CONSENT**

September 2026

Pennsylvania Department of Health
Independent Regulatory Review Commission

**Re: Proposed Rulemaking 10-242; IRRC No. 3490 - Communicable and
Noncommunicable Diseases**

Dear Secretary of Health and Members of the Commission:

Pennsylvania Coalition for Informed Consent (PCIC) submits these comments on proposed Rulemaking 10-242. PCIC is a nonpartisan, grassroots, all-volunteer organization made up of Pennsylvanians committed to informed consent, transparency, and legislative accountability in matters affecting health and individual liberty. For more than a decade, PCIC has educated Pennsylvania families about their rights and responsibilities under the Commonwealth's health and immunization laws. Our members include parents, health care professionals, advocates, and other residents who will be directly affected by the extensive changes proposed in Chapter 27.

We ask the Department to withdraw this proposal and return with a narrower rulemaking that clearly identifies the statutory authority for each material expansion of power. The proposal is more than 500 pages long and reaches disease-control measures, investigations and entry, private medical records, access to students, school exclusion, immunization reporting, prenatal testing, religious accommodation, animals, food and toxins. These issues deserve direct answers in the public record and enforceable safeguards in the regulation itself.

Authority for expanded powers

DOH cites the Disease Prevention and Control Law of 1955 and the Administrative Code as authority for the proposal. PCIC asks DOH to show exactly where those laws authorize each significant new power. A general duty to protect public health is not a substitute for a clear decision by the elected General Assembly on access to homes, personal medical information, schools, or a statewide vaccine registry.

Pennsylvanians need to know what the Department can require, what it cannot require, and how they can challenge a mistake. This proposal leaves too many of those questions unanswered.

- For each new or expanded power, which words in a statute authorize it?
- Which changes carry out existing laws, and which would establish policies the General Assembly has never voted to adopt?
- What stops the broad authority cited by DOH from having no practical limit?
- Why are decisions affecting families, medical records, schools, property, and movement being made by regulation instead of by elected lawmakers?

Disease control measures under Section 27.60

Proposed § 27.60 would authorize the Department or a local health authority to use “any other disease control measure” it considers appropriate for the “surveillance, prevention, containment or mitigation” of disease when deemed necessary to protect the public from infectious agents or toxins. The preamble acknowledges that social distancing and other measures beyond isolation and quarantine are contemplated. It also expressly states that Corman influenced the amendment: the Department proposes to remove the limiting language that prevented the prior catch-all from supporting the statewide school-mask order.

That history makes this a substantive expansion of power, not a clarification. The proposed text supplies no defined severity threshold, emergency declaration, duration, geographic limit, least-restrictive-means requirement, periodic review, legislative approval, or clear avenue for prompt appeal. “Prevention” and “mitigation” could apply before an identified outbreak or declared emergency, while “any other disease control measure” leaves affected citizens unable to know in advance what government may require.

- What specific measures does the Department believe the phrase “any other disease control measure” authorizes—including masking, distancing, closure, gathering limits, compelled testing or restrictions on access to property?
- Why does the proposed rule contain none of the limiting standards that ordinarily accompany coercive emergency powers?
- How will necessity be documented, who reviews that determination, and what prompt process allows an affected person, school, business or religious institution to challenge it?

Related changes to §§ 27.61, 27.65 and 27.66 concern isolation, quarantine, modified quarantine and placarding. Orders that confine a person, restrict a household or publicly mark a property implicate liberty, privacy and reputation. The regulation should specify the evidence required, written notice, access to counsel, prompt

judicial review, periodic reassessment, the standard for release, and safeguards governing the content, placement and removal of placards.

- What procedures guarantee a prompt, neutral hearing before or immediately after an involuntary restriction, and who bears the burden of proving that continued restraint remains necessary?

Investigations entry and medical records

The change in the entry language deserves special attention. Current § 27.152 says a person may not obstruct an official who “seeks to enter” a house or other premises to investigate a case or outbreak judged a potential public-health threat. Proposed § 27.60a says an official “may enter” an apartment, building, school, health care facility, or “other location” when necessary for an investigation. It also permits investigation of any case, outbreak, public-health emergency, or “unusual occurrence.” “Seeks to enter” and “may enter” do not mean the same thing to a homeowner standing at the door. What, exactly, happens if that person says no?

The same expansion appears in medical-record access. Current § 27.152 permits a confidential review during an investigation. Proposed § 27.60e says DOH “shall have access to” records, may request copies, and requires those copies to be sent electronically. The rule does not require the patient to give informed consent or even to be told that their records were obtained. Some public-health disclosures may be lawful without consent, but that does not answer why the proposal lacks clear limits on which records may be taken, who may see them, how long copies are kept, and whether the patient is ever notified.

- When an official “may enter,” is the owner or occupant free to refuse? If not, what process authorizes entry? Why was the existing phrase “seeks to enter” changed?
- Does other location mean that the DOH may enter a place of worship?
- Why can DOH request a copy of a patient’s medical record instead of only the information needed for a specific investigation?
- When will a patient be told that DOH accessed or copied their records, and how can they learn what was obtained and correct a mistake?
- Where are the binding rules on who may see copied records, how they may be shared, and when they must be deleted?

School access partner services and exclusion

Proposed § 27.60c would require a school to provide health officials reasonable and timely access to a person for contact tracing or partner services, including during classes, on school premises or at school functions. School personnel must permit officials to meet and speak privately with a student and may not interfere with rights

described in Pennsylvania's minor-consent statute, 35 P.S. § 10103. The proposal does not expressly require advance parental notice, parental consent, a parent's presence, or notice after the interview.

The proposal's definition of "partner services" expressly includes "testing of partners for HIV or sexually transmitted infections, pre-exposure prophylaxis (PrEP), hepatitis screening and vaccination," as well as referrals involving reproductive health, prenatal care, substance-use treatment, housing, legal and mental-health services. When read together with § 27.60c, this language raises direct questions about what medical services may be discussed, recommended, referred or provided to a student after a private school-based interview, and whether parents will ever be notified.

- Does "hepatitis screening and vaccination" include offering, arranging, referring for or administering hepatitis B vaccination to a minor during or following school-based partner services?
- Does the Department interpret 35 P.S. § 10103 as permitting a minor to consent to hepatitis screening or vaccination without parental knowledge or consent? If so, identify the precise statutory language and explain its application to preventive vaccination rather than diagnosis or treatment of an existing venereal disease.
- Must a parent receive notice before or after a child is privately interviewed, screened, vaccinated or referred for services, and what record of the encounter is created, retained or disclosed?
- What limits prevent information obtained during partner services from being entered into PIERS, PA-NEDSS, school records or another state or interstate system without parental knowledge?
- Because the definition also reaches sexually transmitted infections and prevention services, could the Department include HPV vaccination or another STI-related vaccine within partner services without further legislation or rulemaking? If not, where is that limitation stated in the binding text?

Proposed § 27.71a also expands exclusion of people considered susceptible to diphtheria, measles, mumps, pertussis, rubella, or chickenpox. A healthy child could be kept out of school until the family proves immunity, the child receives a vaccine, or a specified period passes without a new case. In some circumstances that could mean weeks out of school, with another case extending the disruption. What instruction and disability services will the school provide while the child is excluded? What does this cost the family and the school?

There is also a serious drafting error to resolve before this rule moves forward. The proposed measles definition says a susceptible person "was born before December 31, 1956," while the existing measles provision uses "after." The proposed wording appears in several other disease entries as well. DOH should state which word it

meant, why that birth-year test appears in those other entries, and how it reviewed the rest of the exclusion table for similar copy-and-paste errors.

- What statutory text authorizes government officials to obtain private access to a minor at school without advance parental notice?
- How will officials distinguish legally authorized medical consent from questioning, data collection, contact identification and partner-service discussions that may fall outside the minor-consent statute?
- What notice, individualized assessment, appeal, educational-continuity and reasonable-alternative protections apply before a healthy child is excluded?
- How does the Department ensure that religious, moral/ethical and medical exemptions remain meaningful while addressing a documented outbreak?

Access to children's immunization information and on-site education - proposed § 27.77(a)(4)

Proposed § 27.77(a)(4), would replace the current annual reporting of summarized child-care immunization information with a requirement that a caregiver provide DOH, upon request, with the immunization status of each enrolled child. It would also allow DOH to review an individual child's immunization status at the caregiver's location and provide the caregiver with on-site immunization education. This goes beyond receiving a general annual summary and gives DOH access to identifiable information about individual children whenever the Department requests it. What circumstances would permit DOH to request these records? Must there be an outbreak or investigation, or could DOH review them routinely? What information may DOH inspect, copy, retain, or enter into PIERS or another state database? Must parents receive notice before their child's information is provided to DOH, and how can they review the information, correct an error, or challenge an improper disclosure?

DOH explains that vaccination status may be used to determine which children are considered susceptible and may be quarantined. In that context, 'on-site immunization education' could easily become focused on caregivers or families whose children are not considered up to date. Does DOH believe that parents and caregivers are not already receiving complete information and engaging in informed-consent discussions with their children's primary care providers or pediatricians? Why should a state agency insert itself into that relationship, and what information does DOH intend to provide that a child's own health care practitioner has not? If DOH provides vaccine education, it should be offered equally to all families - not selectively directed at families who have delayed or declined a vaccine or who claim a lawful exemption. Complete education should address the risks and potential benefits of

vaccination, known adverse events, the purpose and limitations of VAERS, the right to report an adverse event, medical contraindications, natural immunity where recognized, and Pennsylvania's medical, religious, and strong moral or ethical exemptions. What information will DOH present, who will approve it, and will families be told about their rights as clearly as they are told about recommended vaccines? Education should support informed decisions; it should not be used to pressure caregivers, single out children, discourage lawful exemptions, or substitute DOH's judgment for that of a parent.

PIERS and immunization reporting

Proposed § 27.36 would make reporting every vaccine administration the default for health care practitioners, facilities, and other people authorized to give vaccines, except when the patient declines in writing. The report includes the patient's name, birth date, address, race, ethnicity, and vaccine details. DOH says participation is currently voluntary for most providers. The proposed rule would change that.

Before requiring more people to send records into PIERS, DOH should answer the threshold question: where in Pennsylvania law did the General Assembly give DOH authority to establish and maintain PIERS as a statewide registry of identifiable vaccination records? Act 80 of 2022 directs certain pharmacists to report to a registry already maintained by DOH. That is not the same as a legislative vote establishing the registry and setting the rules for everyone's information.

PCIC favors informed, opt-in consent before a vaccination record goes into PIERS. A written opt-out does little good if a family has never been told the registry exists or that a record is about to be sent. If DOH nevertheless proposes an opt-out system, every parent should receive a clear explanation when a child is born and again before each vaccination. Every adult patient should receive that explanation before a vaccination as well. Notice should explain who can access the record, what it can be used for, and how to decline before transmission, without losing access to care.

- Which statute authorized DOH to establish and maintain PIERS? Please identify the exact language, not merely a law requiring some providers to report to an existing registry.
- Which law authorizes mandatory reporting by every provider covered by proposed § 27.36?
- Who can see, change, download, or share a PIERS record, and how can a patient see who has accessed it?
- How will DOH obtain opt-in consent? If DOH insists on opt-out reporting, how will it give every parent notice at birth and before each vaccination and every adult notice before vaccination?

- Will PIERS records be matched or shared with birth records, schools, disease-reporting systems, other states, or federal systems? Who approved each connection?

PCIC asks DOH to answer these questions publicly and take the issue of registry authority, consent, and privacy to the General Assembly before expanding reporting.

Smallpox vaccine-related adverse-event reporting - proposed § 27.21a

Proposed § 27.21a would add 'smallpox vaccine-related adverse events' as a new reportable condition and require health care practitioners and facilities to report these events to DOH immediately by telephone. DOH discusses this addition on PDF page 163 and places it as item 103 in the reporting chart on PDF page 382. DOH acknowledges that routine smallpox vaccination in the United States ended decades ago after the World Health Organization declared smallpox eradicated in 1980. Its explanation relies primarily on a federal preparedness program begun in 2003 for first responders who might respond to a biological-terrorism event and on adverse-reaction information originating from the 1960s. Why is this being added now as a permanent statewide reporting requirement? How many smallpox vaccinations are currently administered in Pennsylvania, how many related adverse events have occurred, and what present-day evidence demonstrates the need for this new mandate? Which vaccines would DOH classify as 'smallpox vaccines,' what events would qualify as 'vaccine-related,' and would an event have to be caused by the vaccine or merely occur after vaccination?

The proposal never mentions the federal Vaccine Adverse Event Reporting System, even though federal reporting requirements already apply. Under the National Childhood Vaccine Injury Act, health care providers must report to VAERS adverse events listed in the federal Table of Reportable Events when they occur within the specified time and events identified by a vaccine manufacturer as contraindications to additional doses. Manufacturers must report all adverse events that come to their attention. Federal instructions for JYNNEOS and ACAM2000 also direct vaccination providers to report serious adverse events, administration errors, cardiac events such as myocarditis and pericarditis, and specified thromboembolic and neurovascular events. Why does DOH need a separate immediate telephone report when federal reporting requirements already exist for these vaccines? Will providers be expected to report the same event twice - once to DOH and again to VAERS - and, if so, how will the systems be coordinated? If DOH believes state reporting of vaccine adverse events is necessary for patient safety, why does it single out smallpox vaccines while requiring PIERS to collect detailed records of every vaccine administered but creating no comparable state reporting requirement for adverse events following other vaccines?

Surveillance and disease reporting

DOH states that its practitioner reporting list would grow from 52 diseases, infections, and conditions to 125. That is more than double. The proposal also would require emergency departments to send patient information close to real time, no later than 24 hours after arrival, and would let DOH request “other data elements deemed necessary.” Before expanding collection on this scale, DOH should show that it can manage the information responsibly and explain what the additional reporting will accomplish.

- How many additional reports does DOH expect each year from the expanded list and emergency departments, and what will it cost providers and the state?
- How many staff will receive, review, correct, investigate, and securely maintain these reports? Has funding been identified?
- How will DOH identify duplicate reports from a practitioner, laboratory, hospital, and local health department, and prevent the same patient from being counted more than once?

The rule also asks practitioners to report when they suspect a listed condition because of symptoms or appearance. That could create more mistaken or duplicate reports if DOH does not explain what “suspect” means for professionals with different roles and training. No one should be required to diagnose or investigate a condition outside their lawful scope of practice.

- What evidence is enough to trigger a report, and what process corrects a report when a suspected diagnosis is ruled out?

Proposed § 27.5a would also allow identifying information from disease reports to be disclosed when DOH decides that doing so is necessary to inform the public of a communicable-disease risk. Under what circumstances would a name or identifying detail actually be necessary, rather than an anonymous warning? Who makes that decision, what is documented, and how will families be told?

Which version did the State Advisory Health Board approve on July 17, 2025? The package describes a later draft circulated in December 2025 and cites materials dated after the Board meeting. DOH should publish the approved draft, meeting minutes, vote, and a list of later changes so the public can see whether the Board reviewed the text submitted to IRRC.

DOH’s own analysis says it lacks enough information to estimate several costs of expanded reporting and other requirements. That is not an adequate basis for a rule of this size. Please publish expected report volumes, staffing needs, technology and security costs, costs to hospitals and schools, and the expenses families may face when an excluded child needs a practitioner’s assessment before returning.

Religious accommodation

Existing § 27.87(c) recognizes treatment through an accredited practitioner of a well-recognized church or religious denomination relying on prayer or spiritual means when sanitation, isolation and quarantine requirements are satisfied. DOH proposes to delete the provision, explaining that it would recognize religious or spiritual treatment only when “evidence-based.” Because the existing accommodation does not excuse compliance with measures protecting others, deletion materially changes the treatment of religious exercise and should not be presented merely as clarification.

- What documented public-health harm has resulted from the existing accommodation?
- What analysis has DOH conducted under the Pennsylvania Religious Freedom Protection Act, 71 P.S. §§ 2401–2407, including substantial burden, compelling interest and least-restrictive means?
- Why can any legitimate public-health concern not be addressed through a narrower provision preserving religious exercise while maintaining sanitation, isolation and quarantine safeguards?

Animals, food toxins and property

The proposal extends multiple provisions beyond communicable diseases to “conditions,” toxins, public-health emergencies and unusual occurrences. It also broadens animal-control provisions to reach suspected contamination and animal products or materials, including food products. PCIC’s mission includes transparency concerning food, soil, water and air. We recognize a legitimate role for rapid response to genuine contamination, but broad undefined categories can affect farms, food producers, households, property and livelihoods.

- How are “condition,” “toxin,” “unusual occurrence,” “suspected” contamination and “necessary” intervention objectively defined?
- What testing, evidentiary threshold, notice, compensation, hearing and appeal protections apply before animals, products, food or property are restricted, destroyed or rendered unusable?
- Which statutes authorize each expansion beyond communicable disease, and what prevents duplicative or conflicting action by environmental, agricultural and health agencies?

Provisions PCIC supports

PCIC supports genuine technical corrections, clear reporting instructions, and preservation of lawful immunization exemptions. We support recognition of documented immunity and oppose automatic adoption of future vaccine

recommendations without Pennsylvania rulemaking. For vaccine-record reporting, PCIC's position is opt-in consent. If DOH continues to propose opt-out reporting, a choice is meaningful only when every patient or parent receives notice before the record is transmitted.

Vaccine safety reporting

Vaccine safety cannot be an afterthought while the state expands reporting of every vaccine administration. VAERS, the federal Vaccine Adverse Event Reporting System, accepts reports of health problems after vaccination even when no one knows whether a vaccine caused them. Some events already must be reported under federal rules; other serious events are often only encouraged to be reported. DOH should ensure that every vaccine administrator and every practitioner who later evaluates a significant possible reaction knows the requirements, has a clear reporting process, and follows it.

PCIC asks DOH to publish how it checks compliance, how it follows up on safety signals, and what it will do about underreporting. DOH should also seek legislation requiring prompt VAERS reports of clinically significant suspected reactions from institutions that administer vaccines and from institutions that treat patients afterward, even when the vaccination happened elsewhere. Filing a report does not prove causation. It ensures a possible problem is documented and can be investigated. If DOH wants more complete records of vaccinations given, it must put comparable effort into tracking possible harm.

Requested action

For the reasons explained above, PCIC asks the Department and IRRC to:

1. Withdraw proposed Rulemaking 10-242 and bring back routine technical updates separately from new powers that require decisions by the General Assembly.
2. Publish a provision-by-provision authority analysis identifying the precise statutory text supporting each new power and explaining the limiting principle.
3. Identify the law that established and authorized PIERS, and seek legislative direction before expanding mandatory reporting. Require affirmative opt-in consent; at a minimum, give every parent notice at birth and before each vaccination, and every adult notice before vaccination, if an opt-out system is retained.
4. Add objective triggers, severity thresholds, duration and geographic limits, least-restrictive-means requirements, written findings, periodic review and prompt appeal rights to coercive disease-control measures.

5. Explain the change from “seeks to enter” to “may enter”; require appropriate process if entry is refused. Limit access to medical records and tell patients when their information is taken, how it is used, and when it will be deleted.
6. Protect parental notice and involvement before private government interviews of students, except where a clearly identified statute expressly provides otherwise; preserve due process and educational continuity for exclusions.
7. Retain a lawful religious accommodation or provide the analysis required to justify its removal under Pennsylvania law.
8. Publish the staffing and cost estimates for the expanded disease list and emergency-department reporting, the plan for duplicate reports, and the Board-approved draft and record of later changes. Limit the new public-identification exception in § 27.5a to what is genuinely necessary to warn the public, with stated criteria and protection for patient privacy.
9. Explain the present-day need and statutory basis for immediate state reporting of smallpox vaccine-related adverse events, define the reportable standard, and show how state reporting will coordinate with existing federal VAERS duties without unnecessary duplication.
10. For proposed § 27.77(a)(4), define when DOH may request individual child-care immunization records; require parental notice and meaningful privacy safeguards; and ensure that any immunization education is balanced, supports informed consent, explains exemptions, and is offered without targeting or pressure.
11. Extend the public-comment period and hold public hearings before advancing a rulemaking of this breadth.

Conclusion

Public health policy earns trust when government acts under clear authority, respects informed consent and individual rights, and explains the limits of its power. An agency should not use a modernization project to create powers of disputed scope over children, medical records, education, property, religious exercise and daily life. Those decisions belong with the elected General Assembly.

PCIC therefore asks that Rulemaking 10-242 be withdrawn and reconsidered through a transparent process that separates routine technical updates from substantive expansions of government authority.

Respectfully submitted,

Pennsylvania Coalition for Informed Consent (PCIC)

Authorities and primary materials

- Pennsylvania Department of Health, Proposed Rulemaking 10-242, 28 Pa. Code Chapter 27, 56 Pa.B. 5213 (Aug. 8, 2026), including Annex A and Regulatory Analysis Form.
- Disease Prevention and Control Law of 1955, 35 P.S. §§ 521.1–521.21, including § 521.16.
- Administrative Code of 1929, 71 P.S. §§ 532, 536 and 541.
- Pennsylvania Constitution, Article I, § 1.
- *Corman v. Acting Secretary of the Pennsylvania Department of Health*, 266 A.3d 452 (Pa. 2021).
- Pennsylvania Religious Freedom Protection Act, 71 P.S. §§ 2401–2407.
- Act 80 of 2022, amending the Pharmacy Act to require supervising pharmacists to report immunizations to the registry maintained by DOH; current requirements carried forward in Pennsylvania pharmacy law and regulation.
- Pennsylvania Department of Health, Pennsylvania Immunization Electronic Registry System (PIERS) public information pages.
- Vaccine Adverse Event Reporting System, Information for Healthcare Providers (U.S. Department of Health and Human Services).