House of Representatives
Commonwealth of Pennsylvania
Harrisburg

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Via Electronic Mail to irrc@irrc.state.pa.us
Via Electronic Mail to RA-DHCHAPTR27PROPREG@pa.gov

Dear Members of the Independent Regulatory Review Commission:

Re: Rulemaking #10-242: Communicable and Noncommunicable Diseases
IRRC #3490

We, the undersigned, are 85 members of the House of Representatives. We have reviewed the above-referenced proposed regulation as submitted by the Department of Health (Department) regarding revisions to 28 Pa. Code Ch. 27 (relating to communicable and noncommunicable diseases). We submit the following concerns and questions for review and comment to the Department and the Independent Regulatory Review Commission (Commission).

The proposed regulation seeks to update requirements relating to the reporting of communicable and noncommunicable diseases. While we can appreciate the need to report diseases to enable the Department to fulfill its statutory duty to prevent the control and spread of diseases, we are concerned that the Department's proposed regulation goes above and beyond the requirements of applicable law. We also feel that this regulation represents a policy decision of such a substantial nature that it requires legislative review.

As part of its duties to review proposed, final-form, final-omitted, or existing regulations, the Commission shall:

- Determine whether an agency has the statutory authority to promulgate the regulation and whether the regulation conforms to the intention of the General Assembly in the enactment of the statute upon which the regulation is based.
- Determine whether the regulation is in the public interest, which entails the following:
    - The economic or fiscal impacts of the regulation.
    - The protection of the public health, safety, and welfare and the effect on this Commonwealth's natural resources.
    - The clarity, feasibility, and reasonableness of the regulation, which includes the reasonableness of requirements, implementation procedures, and timetables for compliance by the general public and private sectors.
    - Whether the regulation represents a policy decision of such a substantial nature that it requires legislative review.
    - Comments, objections, or recommendations of a committee.
    - Compliance with the provisions of the Regulatory Review Act or the regulations of the commission in promulgating the regulation.
    - Whether the regulation is supported by acceptable data.
    - Whether a less costly or less intrusive alternative method of achieving the goal of the regulation has been considered for regulations impacting small business.[1]

The Department's proposed regulation is problematic in many ways. The regulation:

- Does not comply with the Department's statutory authority.
- Is overly burdensome on the regulated community.
- Does not factor in costs to the regulated community.
- Creates requirements that are far reaching.
- Does not require the least restrictive means upon the regulated community.
- Expands judicial interpretations of the Department's authority.
- Authorizes the Department to obtain data it does not need, including unprecedented access to medical records.
- Gives the Department unquestioned authority over adults, minors, dwellings, and schools.
- Eviscerates long-standing recognition of medical, religious, and philosophical exemptions.

By submission of these comments, we are requesting a formal response from the Department and review by the Commission. For reference, we have numbered our questions below and then offered an explanation regarding our questions. Our comment letter is constructed as follows with hyperlinks available by clicking on a page number below:

[1] See section 5.2 of the Regulatory Review Act, 71 P.S. § 745.5b (relating to criteria for review of regulations).

TOPIC **PAGE NUMBER**

A. Use of the Term "Public Health Emergency"

1. How does the term "public health emergency" comport with the statutorily recognized "disaster emergency"?

Throughout the regulatory package, the Department uses the term "public health emergency." In fact, in doing a search for this term in the Department's 502-page regulatory packet, that term came up 50 times.

We would note that under 35 Pa.C.S. § 7301(c), the Governor may declare a "declaration of disaster emergency." While this includes health-related concerns, there is no statute for an official "public health emergency." This limitation is further evidenced by bills that were introduced by members of the General Assembly to authorize the Governor to declare public health emergencies (see for instance, SB 1001 from the 2017-2018 legislative session and SB 633 from the 2019-2020

legislative session). We seek clarification on whether this term comports with current statutory authority.

B. "Individual" vs. "Person"

2. We request that the Commission inquire about the use of "person" vs. "individual" by the Department to ensure that the proper word is being used in various parts of the regulation.

The Department uses the term "person" in various parts of the regulation when it seems the proper term to be used should be "individual." Under the Statutory Construction Act, 1 Pa.C.S. § 1991, the term "person" encompasses more than human beings. As an example, we direct the Commission and the Department to proposed § 27.203(a) and (b).

C. "Pregnant Individual," "Birthing Individual," and "Postpartum Individual"

3. Where is the Department's statutory authority to create new terms that are not recognized under the enabling statutes?

While not surprising, the Department has chosen to eliminate words and terms such as "mother," "pregnant woman," and "mother of a newborn" and replace them with "pregnant individual" (used 53 times in the regulatory package), "birthing individual" (used twice in the regulatory package), and "postpartum individual" (used eight times in the regulatory package).

This Administration and some members of the General Assembly have tried to create new terminology that was not enacted by the General Assembly. The Department is now attempting to circumvent the General Assembly by putting statutorily unrecognized terms into regulations that have the force and effect of law. Essentially, the Department is seeking to do what could not be done legislatively, namely, the elimination of women and mothers from our lexicon.

In promulgating regulations, the Department must comply with the statutes that give it authority to promulgate said regulations. We direct the Commission and the Department first to the Statutory Construction Act, which requires an agency to ascertain and effectuate the intention of the General Assembly (see, specifically, 1 Pa.C.S. § 1921(a)). We note that it is the intention of the General Assembly that must be ascertained, not the intention of the Governor, his Administration, or interest groups that seek to make their own changes. Second, we direct the Commission and the Department to the primary statute that provides the Department with authority to promulgate this regulation, namely, the Disease Prevention and Control Law of 1955. In that law, the terms "pregnant individual," "birthing individual," and "postpartum individual" are not used. In fact, the word "individual" is only used one time in the statute and is not meant to specify

only a male or a female (see section 15.1(a)(3)(ii)). More importantly, the term "pregnant mother" is used three times in the statute (see section 13(a)).

The Department can argue all day long that it is using current or contemporary terminology or that it is trying to create uniformity or clarity in its regulation. Try as they might, they cannot usurp the role of the General Assembly in determining words, phrases, and terms that are to be used by creating its own terms through the regulatory process. We request the Commission inquire with the Department about these new terms.

D. "Prevention," "Containment, and "Mitigation"

4. What are the definitions for "prevention," "containment," and "mitigation"?

The proposed regulation will allow the Department to implement disease control measures not only for surveillance, but also for the "prevention, containment, or mitigation" of a disease. (see proposed § 27.60(a) on page 417 of the regulatory package). We are concerned that there are no proposed definitions for these words. While the Department may feel these terms are self-explanatory, the regulated community should have notice of what the Department thinks these terms mean for purposes of this regulation. We request that the Commission inquire into the lack of definitions.

E. Disease Control Measures

5. Does the Department consider masking (whether in schools, the community, private residences, private businesses, in public, or generally anywhere) a disease control measure that the Department may use as an option if this proposed regulatory package is approved?

6. Does the Department consider mandated vaccinations of any type as a disease control measure that the Department may use as an option if this proposed regulatory package is approved?

The Department does not delineate nor specify potential disease control measures such as masking and vaccination in its proposed regulation. The regulated community must be provided with notice regarding what the Department may seek to do to contain a disease within the Commonwealth.

F. Conditions

7. Do mental health concerns of an individual constitute a "condition" or other qualifying event under the proposed regulation that would trigger "surveillance, prevention, containment, or mitigation" by the Department if this proposed regulatory package is approved? If so, will disease control measures by the Department include involuntary

commitment of the individual by the Department to a mental health institution or other facility?

8. Can a "condition," as defined by the Department, when accompanied by a disease outbreak, authorize the Department to institute disease control measures upon an individual for mere susceptibility?

In proposed § 27.1, the Department defines "condition" as a "noninfectious medical ailment or other health-related event." As to the first question, we seek clarification on whether mental health concerns constitute a condition under this regulation. As to the second question, as an example, if an individual has chronic obstructive pulmonary disease (COPD) and there is a new COVID-19 outbreak, will this event be enough to authorize the Department to institute a disease control measure on that individual simply because they have COPD and COVID-19 may worsen that individual's health status?

9. What is considered a "noninfectious medical ailment or other health-related event"?

Specifically, as to the definition of "condition," this definition is very broad, and clarity is needed on what the Department considers a condition. This definition gives the Department wide latitude in imposing disease control measures. We request more specificity under this definition.

G. <u>Costs to the Regulated Community</u>

10. What are the potential costs for the regulated community?

The Regulatory Review Act requires the Commission to determine the economic and fiscal impacts of the regulation, the reasonableness of the regulation, and whether a less costly or less intrusive alternative method of achieving the goal of the regulation has been considered for regulations impacting small business.[2] The Commission cannot adequately do this without sufficient information being supplied by the Department. For instance, if the Department has not done so already, it can reach out to organizations such as the Hospital & Healthsystem Association of Pennsylvania, the Pennsylvania Medical Society, and other statewide organizations representing health care systems, health care facilities, health care practitioners, and other entities and individuals affected by this regulation.

In the Regulatory Analysis Form, the Department indicates in multiple places that there will be zero costs to the regulated community, whether because there is insufficient data, because fiscal costs will vary, or due to the establishment of a new system.

[2] See section 5.2 of the Regulatory Review Act, 71 P.S. § 745.5b (relating to criteria for review of regulations).

On page 25 of the RAF regarding health care practitioners and health care facilities, the Department states, in part:

> The Department does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients seen at a location, the number of reportable diseases diagnosed at each location, and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

Beginning on page 32 of the Regulatory Analysis Form (RAF), the Department indicated that there will be zero costs to the regulated community. We find it hard to believe that there will not be an increased cost to the regulated community when factoring in time, submission requirements, and follow up with patients, to name a few.

The Department uses similar rationale in other places to estimate no fiscal impact or savings for the regulated community, including clinical laboratories, schools, colleges, universities, childcare group settings, veterinarians, and the general public. Further, the Department provides no estimate of the fiscal impact for § 27.37, which will require all health care practitioners and health care facilities to report certain birth defects and congenital anomalies to the Department. The Department indicates on page 35 of the regulatory package that these "practitioners and facilities will need to establish a system for reporting birth defects to the Department's newly created electronic birth defects registry. This may involve creating an electronic system for automated reporting or allocating staff to manually submit data to the Department's birth defects registry."

We request the Department make a concerted effort to determine the costs for the regulated community.

H. <u>Increase in Reportable Conditions</u>

11. Why isn't the Department proposing to phase in the increased reportable conditions?

If promulgated, the proposed regulation will require the reporting of additional diseases, infections, and conditions to the Department as follows:

- Health care practitioners: an additional 73 diseases, infections, and conditions.
- Clinical laboratories: an additional 53 diseases, infections, and conditions.
- Veterinarians: an additional 4 diseases, infections, and conditions found in animals.
- Health care practitioners and health care facilities: 6 sexually transmitted diseases as well as tuberculosis.

- Health care practitioners and health care facilities: animal bites, scratches, or contamination of open wounds or mucous membranes.

In addition, the proposed regulation will require:

- Clinical, research, or commercial laboratories that possess, use, or transfer select agents or toxins to report release, exposure, loss, or theft of such.
- Hospitals to report emergency department visit data. The Department indicated that all hospitals are already voluntarily reporting this data to the Department, but this regulation will make it mandatory.

We question why the Department did not phase in the increase in reportable conditions and whether the Department considered a less costly or less intrusive alternative method to achieving the goals of the regulation. This dramatic increase will drive up administrative burdens, staffing needs, and operational costs across the health care system, which in turn will be passed on to patients. This issue further bolsters the need for a more accurate analysis of the costs to the regulated community.

I. Reporting Immunization Data to the Department

12. Why does the opt-out language not require more information and documentation?

In the proposed regulation at § 27.36, the Department seeks to implement a new requirement, namely, that persons authorized to administer immunizations to report each immunization administration in all counties of the Commonwealth (except Philadelphia) to the Department's designated immunization information system. While the Department indicates that many providers are voluntarily providing this information, reporting will become mandatory unless a patient opts out of this requirement.

While the Department provides an opt-out for the patient, the proposed regulation does not require health care practitioners, facilities, and authorized individuals to inform the patient that they may opt out, that their data is being collected, and how it is being used. Further, the proposed regulation does not provide what information must be conveyed to the patient. In essence, patients will be required to know they may opt out, or at least question whether they may do so. Many patients will not think about this while seeing their health care provider, so it is incumbent on the regulated community to be required to inform patients of their right to opt out with no adverse consequences from the Department or the provider. There should be a form that contains specific language that memorializes these requirements and a copy of the opt out form should be made available to the patient. The patient should be made aware that data is being collected and how it is being used. Without these measures, there is no assurance that a patient will have fully consented to this new

requirement. We request changes to these provisions to ensure that patients are provided with clear opt-out information and specific knowledge of data collection and its use.

13. What does the Department plan to do with this new data?

We also question what the Department plans to do with this new data. While reporting is currently voluntary, once it becomes mandatory, the Department will have access to a vast majority of Commonwealth residents' immunization history. Will the Department use this data to contact individuals to recommend immunizations an individual does not have, will they use this information to report a parent for not immunizing a child, or is it merely being used for statistical purposes? We request further clarification on why this data is needed and how it will be used.

J. <u>Reporting Birth Defects and Congenital Anomalies</u>

14. Why does the opt-out language not require more information and documentation?

Like our concerns regarding § 27.36, we question why there is no opt-out language for the reporting of a birth defect under proposed § 27.37 and that there is nothing in the regulation that requires a patient to be informed that data is being collected and how it is being used. This situation can be very emotional for the mother and father, so, like our concerns with § 27.36, this requirement must be added, in addition to informing the patient that data is being collected and how it is being used.

K. <u>Birth Defects Registry</u>

15. What is the Department's rationale for creating a birth defects registry?

The Department's rationale for its creation is "to identify potential causes of birth defects and thus, work towards preventing them." We are requesting more information on how the Department plans to prevent birth defects by creating this registry. We are concerned this registry is simply a tool for the Department to gain more personal information than is necessary to implement its statutory mandate.

16. Does the Department's proposal include aborted fetuses?

On page 246 of the regulatory package, the Department states that:

> In paragraph (1), the Department proposes to require reporting for infants who are born alive and are diagnosed before their first birthday. This would include infants who are born alive but die before their first birthday and are diagnosed with a birth defect or anomaly at the time of death. In paragraph (2), the Department proposes to require reporting for fetuses that are not

> born alive but have completed 19 weeks of gestation. In the absence of a gestational age estimate, a congenital anomaly in a fetus that is not born alive shall be reported if the fetus had a weight of at least 500 grams.
>
> The Department proposes such reporting to account for congenital anomalies which developed during pregnancy and may have attributed to the infant's death.

It is not clear whether the Department considers aborted fetuses to fall under this reporting requirement, so we request clarification on this issue.

L. <u>Clinical Laboratories</u>

17. What health equity initiatives is the Department proposing by requiring an individual's date of birth, gender, race, and ethnicity, and how is this data going to aid the Department in preventing and controlling the spread of diseases across the Commonwealth?

Proposed § 27.22(c) will require clinical laboratories to collect more patient data to report to the Department. Under this proposal, clinical laboratories will now have to report birth, gender, race, ethnicity, and pregnancy status. The Department asserts that while this may require more work for clinical laboratories, "this will benefit overall patient health by promoting health equity and accurate approaches to prevent disease spread." (see page 24 of the regulatory package). Whatever health equity measures the Department is attempting to pursue, the regulated community should not be the collector of this information on behalf of the Department under threat of violating a regulation. We seek clarification on the Department's health equity initiatives.

18. Why does the Department need the pregnancy status of a woman?

What purpose does this serve for the Department? Does the Department plan to speak to the woman's health care practitioner about her pregnancy? Will the Department discuss alternatives with the pregnant woman other than carrying the baby to term? We seek further information on the reasons the Department needs this information for purposes of fulfilling its statutory mandates.

19. What designations will the Department use for gender and/or sex?

Will the Department use only male or female, or will it use additional designations that are not set forth in statute? We request a list of the designations the Department will be using.

M. <u>Investigation of Cases</u>

20. Does "building" or "other location" include a private home or residence (including a townhouse or condominium)?

Section 27.60a gives the Department or local health authority absolute authority to enter premises for purposes of carrying out an investigation. We request clarification on what constitutes a "building" or "other location" under this regulation, including what other types of private residences or dwellings will be subject to this regulation.

21. Does "apartment" include the common areas of an apartment building only (such as the lobby) or does it include the private apartment dwelling of a tenant?

Under § 27.60b, regarding apartments, we request clarification whether this requirement includes the personal dwelling of the tenant or just common areas like the lobby.

22. Who is an authorized representative of the Department or local health authority and what information must they present?

We are concerned that the Department's proposal simply requires the Department or local health authority representative to "present documentation to establish that they are an authorized representative of the Department or local health authority." This proposal does not:

- Identify who is considered an authorized representative.
- Require the Department or local health authority to present any documentation regarding the outbreak or disease being investigated.
- Require the reasons why the dwelling is being searched, nor other matters pertinent to the search of the dwelling.
- Require any judicial authorization, such as a search warrant.

The official simply must show identification that they work for the Department or local health authority. This authorization is too broad and is ripe for representatives to conduct random searches and investigations of an individual's dwelling without documentation establishing, at minimum, probable cause for the investigation. We request the Commission inquire into this issue further and require stricter parameters for access to a private dwelling of any kind, including a valid search warrant.

N. <u>Contact Tracing and Partner Services</u>

23. Why is the Department proposing a regulation that a minor of any age can be confronted by a government official, in private, on school grounds, without parental notification and presence, and without a school official present?

The proposed regulation under § 27.60c imposes new sweeping mandates on school districts, brick-and-mortar charter schools, cyber charter schools, colleges and universities, and childcare group settings. Under this proposal, the Department concedes that "none of the states surrounding Pennsylvania address partner services or contact tracing with their communicable disease regulations." (see page 7 of the regulatory package). Nonetheless, the Department seeks to require schools to provide it with unimpeded access to minors without notification to a parent or guardian or even with a school official present.

Under proposed § 27.60c, a school must provide the Department or local health authority with reasonable and timely access to a person for the purpose of contact tracing or partner services, including access when classes are in session or at any other time the person is present at school, on school premises, or attending a school function. In addition, the Department or local health authority will be authorized to meet and speak with a student or other person in private, and the school may not interfere with the student or the student's ability to exercise their right to give consent under the Commonwealth's law regarding minor's consent to treatment.

We have several concerns about this new proposal. While we understand the Commonwealth's law regarding consent to treat, it is important to recognize that the Department's proposal will affect all ages and grade levels in a school. Under the Department's proposal, a school conceivably would have to give the Department access to any student at any grade level, in private, without parental notification or presence, or even the presence of a school official. This is extremely disturbing and lacks any recognition by the Department that regardless of their purported statutory authority, there are still parameters that need to be in place, particularly when it involves minors. This proposal is an overreach by the Department and contact tracing can still be accomplished in a less intrusive manner.

This proposal puts schools at risk of violating a regulatory requirement versus their duty to protect students in their care and notifying parents or guardians as the schools determine is appropriate. The Department should not have unfettered access to students without the need to have the school's approval, without a parent or guardian being notified, and without a parent or guardian being present while their child is questioned by the Department. For any child, but particularly our youngest children, this could be a scary situation made all the worse because a parent or guardian is not there to be with the child. No child, whether in class, at a school dance, or at sports practice, should be confronted with the requirement that they must talk to a government official alone and possibly be talked into receiving a vaccine or other form of treatment. This goes beyond what is

needed to do contact tracing and does not consider religious, medical, or philosophical objections to vaccinations. We implore the Commission to require more protection for students, and we urge the Department to remove this proposal.

24. Will Department and local health authority officials have proper clearances?

Under the Child Protective Services Law (CPSL), 23 Pa.C.S. Ch. 63, specified individuals or groups are required to have employment clearances. One of those groups consists of employees having direct contract with children. Under the CPSL, the definition of "direct contact with children" means "the care, supervision, guidance or control of children or routine interaction with children." Under the Department's proposed regulation, it is apparent that a Department official will have "supervision, guidance or control" of a child during the time when the official is questioning the child, in private, about contact tracing or partner services. We are asking for clarification whether Department employees who will be questioning children have the required background clearances specified in the CPSL.

O. <u>Access to Medical Records</u>

25. How will the Department ensure confidentiality of electronic records?

26. Who will be able to review the electronic records and how will the records be destroyed?

The Department proposes to revise 28 Pa. Code § 27.152 (relating to investigation of cases and outbreaks) specifically related to medical records. Current § 27.152(c) provides the following:

> (c) In the course of conducting an investigation of a case or outbreak, the authorized representative of the Department or local health authority may conduct a confidential review of medical records. A person may not interfere with or obstruct this review.

The Department proposes to replace that section with new § 27.60(e) (relating to confidential review of patient medical records) as follows:

> (a) In the course of conducting an investigation, the Department or local health authority, shall have access to and may conduct a confidential review of patient medical records maintained by health care practitioners, hospitals and other health care facilities. Copies of medical records may be requested by the Department or local health authority and shall be transmitted electronically in a secure manner acceptable to the Department or local health authority.

> (b) A person may not obstruct or interfere with, the review of patient medical records by the Department or local health authority.
> (see page 419 of the regulatory package).

The Department seeks carte blanche electronic submission of documents by the regulated community while investigating under this chapter. The protections surrounding this proposed rule are scant. How will they be transmitted in a way that complies with federal and state privacy rules? How will they be stored? When will those records be destroyed and how will they be destroyed?

27. What electronic records may the Department review?

Further complicating the Department's access to medical records, and in particular electronic records, is the lack of limits to the Department's access. We are concerned that the Department will conduct a fishing expedition with an individual's medical records. There are no protections cited to ensure the Department may only review specific records related to a communicable disease under a specified circumstance. It is easy to think that a Department official will request more records than needed and review an individual's medical records under the guise of an investigation. This situation will put health care providers in an untenable situation, as their licenses to practice or to operate may be affected if they refuse to provide this information or if they ask for more information from the Department. We request further clarification on this issue.

28. Does access to medical records include access to a school nurse's medical records of a student?

The Department's proposed regulation includes the records of a "health care practitioner," which includes a nurse. Is this proposal limited to a nurse of a health system, hospital, or similar facility, or does it include practitioners outside of a health system such as a school nurse? We request clarification on this issue.

P. <u>Religious Accommodations</u>

29. What evidence-based treatments will the Department rely on when approving a church, religious or spiritual treatment?

Under proposed § 27.87, the Department seeks to delete current § 27.87(c), which reads as follows:

> For the purpose of this section, treatment approved by the Department or by a local health authority may include treatment by an accredited practitioner of a well-recognized church or religious denomination which relies on prayer or spiritual means alone for healing, if requirements relating to sanitation, isolation or quarantine are satisfied.

The Department states that it relies on "evidence-based treatments and would only approve of a church, religious or spiritual treatment to the extent that it is evidence-based." (see page 318 of the regulatory package). We are concerned that this proposed requirement eliminates long-standing religious accommodation and infringes on free exercise rights guaranteed by our state and federal constitutions. We are further concerned that the Department does not elaborate on what it considers evidence-based treatment, which will allow the Department to alter its stance on this issue. Does "evidence-based" mean it must come from a government agency, whether federal or state? A national stakeholder group such as a physician organization? The Department itself? This proposal is too open-ended and is ripe for abuse as the Department sees fit and only seeks to erode the Commonwealth's long-standing support of religious-based freedom at the expense of an overreaching state bureaucracy. We seek clarification on this issue.

Q. <u>Prenatal Examinations</u>

30. Why is the Department requiring testing for all pregnant women regardless of the rate of infection in a given population?

The Department proposes to require all pregnant women to undergo a blood test for syphilis (§ 27.89), hepatitis B (§ 27.99), hepatitis C (§ 27.99a; a new requirement), and HIV (§ 27.99b; a new requirement) unless the pregnant woman objects. Specific to syphilis, this proposal removes the current regulatory requirement that syphilis testing only occurs where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given population for which the CDC has determined it is cost-effective to require special precautions.

As with many of the other concerns that we have with this proposed regulation, the Department has taken the stance that a one-size fits all requirement is needed because it has determined that "testing is necessary for all pregnant individuals in the third trimester." (see page 319 of the regulatory package). This proposal does not consider up-to-date syphilis numbers for a given community, does not address how an objection may occur, how a practitioner must inform that pregnant woman that she may object without repercussion, and payment for the test. Further, this proposal does not take into consideration future changes from the CDC. We request clarification on this issue.

R. <u>Animal Products</u>

31. Will the Department impose disease control measures on agricultural products such as unpasteurized cheese or raw milk?

The Department's proposed regulation under § 27.191 would extend restrictions to when animals and animal products are "suspected or known to be contaminated by a pathogen that poses a threat

to human health." (see page 333 of the regulatory package). We are concerned that this proposal could extend to agricultural products that the Department may disagree with, such as unpasteurized cheese or raw milk, and in turn, the Department could prohibit those products from being sold or given to other individuals. This proposal has the potential to harm our agricultural community and consumer choice (i.e., the economic and fiscal impacts of the regulation). We request more clarity from the Department.

S. Susceptibility

The Department proposes to implement disease control measures based on susceptibility alone for six diseases – diphtheria, measles, mumps, pertussis (whooping cough), rubella, and varicella (chicken pox). Generally, the Department justifies these actions for severe, vaccine preventable diseases. We note that susceptibility to measles is contained in the Department's current regulations and that this proposal seeks to revise those standards for measles.

a. *Measles* (proposed § 27.71a(15)(ii); see page 436 of the regulatory package)

32. Must an individual meet all four factors to be considered susceptible to measles or only one of the factors?

The Department proposes to increase the number of days a person may be excluded from 14 days to 21 days. The Department delineates factors for susceptibility as follows:

> (ii) The Department may, in the course of conducting disease control measures under Subchapter C, exclude a person susceptible for measles from a school, college, university or child care group setting until the person provides proof that they are not susceptible, receives a vaccine for measles, or when no cases of measles have occurred in the specific school, college, university or child care group setting for 21 days.
>
> A person susceptible for measles includes a person who:
> - presents no history of two age-appropriate doses of measles vaccination while 12 months of age or older, with the doses given at least 1 month apart;
> - does not have a diagnosis of measles disease as set forth in a written record from a health care practitioner acting within the scope of their practice;
> - does not demonstrate serological evidence of measles immunity (the presence of antibodies to measles determined by a hemagglutination inhibition test or other comparable test); and
> - was born before December 31, 1956.

Under the current regulation at 28 Pa. Code 27.160(b)(1) (relating to special requirements for measles), the Department defines susceptibility as follows:

> (1) Ascertain which children and staff persons are presumed susceptibles. A presumed susceptible is a person **who fits into all of the following categories**:
> (i) Presents no history of two doses of measles vaccination, separated by at least 1 month, while 12 months of age or older.
> (ii) Does not demonstrate serological evidence of measles immunity. The serological evidence is the presence of antibody to measles determined by the hemagglutination inhibition test or a comparable test.
> (iii) Was born after December 31, 1956.
> (Emphasis added).

Under current regulations, the Department requires an individual to meet every condition to be considered susceptible. Under the proposed regulation for each of the six diseases, the Department does not include the language "who fits into all of the following categories" and instead uses the language "a person who." This leads us to believe that an individual only needs to meet one of the conditions to be considered susceptible. If not, the Department could have simply carried forward existing language.

We request clarification on whether all four factors must be met or just one factor.

33. Why does the proposed regulation require the individual to be born "before" December 31, 1956, yet the current regulation requires the individual to be born "after" December 31, 1956?

The Department's existing regulations (see 28 Pa. Code § 27.160) already contain requirements for measles. In subsection (b)(1)(iii), it requires a person to be born "after" December 31, 1956. We request clarification on this proposed change.

34. Is "or" or "and" the correct word that the Department is using for its factors?

The Department's proposal regarding susceptibility conflicts between its explanation and the actual language in the proposal. In its explanation (see page 280 of the regulatory package), the Department uses the word "or" before the factor regarding when an individual was born. In the proposed text of the regulation, the Department uses the word "and." We request clarification on this conflict.

35. How do the factors enumerated for susceptibility to measles comply with the Commonwealth's recognized exemptions for medical, religious, or philosophical objections?

We seek clarification regarding an individual who objects on any of those grounds whether they may still be considered susceptible and thus be subject to disease control measures. Per the Department's explanation, an individual is subject to exclusion due, in part, to an "incomplete or absent history of vaccination or lack of natural immunity." This further bolsters our concerns that this regulation essentially eliminates recognized exemptions and will force individuals to carry vaccine cards. We request that the Commission seek answers from the Department on this issue.

b. *Diphtheria* (proposed § 27.71a(7)(ii); see page 432 of the regulatory package)
c. *Mumps* (proposed § 27.71a(19)(ii); see page 438 of the regulatory package)
d. *Pertussis* (proposed § 27.71a(21)(iii); see page 440 of the regulatory package)
e. *Rubella* (proposed § 27.71a(24)(ii); page 444 of the regulatory package)
f. *Varicella (proposed § 27.21a(34)(ii); page 453 of the regulatory package)*

Given that our questions and comments are the same for each of the five diseases listed above, we have combined our questions and comments below. We request responses for each of the five diseases.

36. Must an individual meet all four factors for these five newly listed diseases to be considered susceptible or only one of the factors?

For each of these five diseases, the proposed regulation states that "a person susceptible for (name of disease) includes a person who…" Like our concern for measles, we seek clarification whether an individual must meet every factor listed for each of the five diseases to be considered susceptibility or whether they only need to meet one of the factors.

37. How do the factors enumerated for susceptibility comply with the Commonwealth's recognized exemptions for medical, religious, or philosophical objections?

We seek clarification regarding an individual who objects on any of those grounds whether they may still be considered susceptible and thus be subject to disease control measures. Per the Department's explanation, an individual is subject to exclusion due, in part, to an "incomplete or absent history of vaccination or lack of natural immunity." This further bolsters our concerns that this regulation essentially eliminates recognized exemptions and will force individuals to carry vaccine cards. We request that the Commission seek answers from the Department on this issue.

38. Why is it in the public interest in 2026 to add these five diseases for mere susceptibility?

We recognize that the Department's current regulations (see 28 Pa. Code § 27.160 (relating to special requirements for measles)) already contain provisions regarding susceptibility to measles. As such, we will focus our questions on the proposed addition of the five other diseases.

Diphtheria
Per the preamble to this regulation, the CDC has listed diphtheria as a nationally notifiable disease since 1944 (see page 79 of the regulatory package). The Department further cites an outbreak of diphtheria in the 1990s in the former Soviet Union.

Mumps
Mumps became a national notifiable disease after the mumps vaccination program started in 1967.[3]

Pertussis
Per the CDC, pertussis was one of the most common childhood diseases and a major cause of childhood mortality in the United States. Before the availability of the pertussis vaccine in the 1940s, more than 200,000 cases of pertussis were reported annually.[4]

Rubella
The rubella vaccine was licensed in the United States in 1969. Prior to that year, rubella was a common disease that occurred primarily in young children. Epidemics at that time occurred every six to nine years.[5]

Varicella
Varicella became a reportable disease in the United States in 1972, with states reporting weekly aggregate data to the National Notifiable Disease Surveillance System. In 1995, the varicella vaccine was licensed and added to the routine childhood vaccination schedule. After its removal from the national notifiable diseases list in 1981, varicella was added back to that list in 2003.[6]

We note that the Department's justification paints the proverbial "scarlet letter" on many citizens, but particularly those citizens who are unvaccinated, whether by choice or because of a recognized exemption (medical, religious, or philosophical).

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[3] https://www.cdc.gov/mumps/outbreaks/index.html. Accessed on September 2, 2026.
[4] https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-16-pertussis.html. Accessed on September 2, 2026.
[5] https://www.cdc.gov/rubella/hcp/clinical-overview/index.html. Accessed on September 2, 2026.
[6] https://restoredcdc.org/www.cdc.gov/mmwr/preview/mmwrhtml/mm5541a4.htm. Accessed on September 2, 2026.

One of the factors the Commission must consider is whether a regulation is in the public interest. We question why these diseases are being added to the list of reportable conditions for susceptibility when these diseases are not new to the Commonwealth, let alone the United States. When the Department last revised this regulation substantially (2002), these diseases could have been added then for susceptibility. Instead, 24 years later, the Department has determined that adding these diseases, based on mere susceptibility, is needed now. While we understand the Department may not be able to address why these diseases were not added when the regulation was revised in 2002, it does beg the questions of why they were not and why they are being added now. As such, we request the Commission to consider why it is in the public interest to do so now. We seek clarification of our concerns.

T. Compliance with Corman v. Acting Sec'y of Pennsylvania Dep't of Health, 266 A.3d 452 (Pa. 2021)

39. How does the limiting language in current § 27.60(b) comport with the Department's proposed regulation?

The Department proposes to expand its disease control measures in the wake of the *Corman* decision where the Pennsylvania Supreme Court ruled that the Department's disease control measures were limited primarily to surveillance due to its existing regulations.

Focusing on the Department's rationale for expanding its disease control measures, the Department cites to one sentence in the Court's opinion for the proposition that the Department simply needs to promulgate a different regulation and all is well ("Of course, the Department has the power to promulgate a different regulation, or to amend this one, to expressly authorize mask mandates or to strip the "any other disease control measure" catch-all of its limiting language.").[7] However, it is interesting to note what the Department left out of its rationale as much as it is interesting to note what the Department chose to include. The full explanation used in the *Corman* opinion states:

> …Of course, the Department has the power to promulgate a different regulation, or to amend this one, to expressly authorize mask mandates or to strip the "any other disease control measure" catch-all of its limiting language." The same goes for the Department's self-imposed "contact" metric, which restricts the class of individuals who can be subjected to a modified quarantine. And nothing we say here today should be construed as limiting the Department's authority to amend or promulgate regulations in

[7] See pages 3 and 251 of the regulatory package, respectively. On page 3, the Department admits that "The foregoing decision influenced the Department's proposed amendments to this subsection, which propose to add "prevention, containment or mitigation" as justifications for the implementation of all disease control measures available to the Department under the Disease Prevention and Control Law."

accordance with the Disease Prevention and Control Law and any other applicable regulatory statute. As it stands now, though, we are constrained by the terms of the regulation before us, not the regulation that the Secretary might have hoped the Department had written.

Further action by the Department may be necessary to meet the moment, in any event, as it appears Section 27.60(b) of the regulation further cabins the Department's discretion to "determine the appropriate disease control measure" in a given situation by requiring that its determination be "based upon the disease or infection, the patient's circumstances, the type of facility available and any other available information relating to the patient and the disease or infection." 28 Pa. Code § 27.60(b) (emphasis added). In focusing upon the individual "patient," these criteria further suggest that the aim of the regulation as a whole is targeted control measures responsive to discrete cases of exposure or infection. So while the nature of the disease certainly is relevant when deciding what measures are appropriate to control its spread, this language reinforces the notion that this regulation, as written, was not intended for blanket control measures, but rather case-specific restrictions.

Notably, the Department has not, in the past, relied exclusively upon the regulation's catch-all in developing "other control measures." For instance, the Department has promulgated a distinct regulation for "placarding"—a form of public-warning-cum-shaming in which the Department posts signs on the residences of those "case[s], [ ] contact[s] or others" whom "the Department ... has reason to believe ... will not fully comply with the isolation or quarantine." 28 Pa. Code § 27.66 ("Placarding"). The Department similarly has provided for the "segregation" of contacts of a person or animal with a communicable disease by regulation, which vaguely entails "[t]he separation for special control or observation of one or more persons or animals from other persons or animals to facilitate the control of a communicable disease." Id. § 27.1 (defining "segregation"). And as indicated, the Department has crafted a number of regulations dealing with isolation and quarantine generally, as well as measures for controlling the spread of disease in schools and childcare facilities in particular. The Department's ability to develop comprehensive regulations for disease control in schools is apparent. Presently, we see no obvious reason why it cannot formally add masks to that list in due course.
Corman, 266 A.3d 452, 484–85 (Pa. 2021).

The Department is seeking to increase its regulatory authority with a broad brush. The limiting language in current § 27.60(b) is tied to the patient, and the proposed regulation fails to specifically address this. The Department also has failed to adequately address its lack of utilizing the current regulation's catch-all language to develop new disease control measures. We request clarification for these concerns.

40. How is the Department's proposal tied to a potential masking or vaccine mandate?

While we will vehemently oppose any sort of regulatory mandate to mask citizens, force vaccinations, or any other overly restrictive means the Department wishes to hold over the citizens of this Commonwealth in an attempt to move us into a submissive society, if the Department is seeking to have that authority, it needs to openly and honestly state that in the regulation as opposed to using broad terms that it one day hopes to use to force masks, vaccines, or other disease control measures upon its fellow citizens. However, even if the Department seeks specifically to add masks or vaccines to this regulatory package, the Department must do so with limiting parameters that tie it directly to the language and purpose of the law. In essence, the Department should tie any disease control measure to the patient and not attempt to create a one-size fits all solution that does not consider the disease that is spreading, its transmission rates, what portion of the population is being affected, the efficacy of the control measure, and whether there are less intrusive options available. We are seeking a specific answer from the Department regarding its intent on including mask mandates and mandated vaccinations in this regulatory package.

We urge the Commission to explore this issue further with the Department and demand more openness, transparency, and explanation from the Department regarding the Court's decision and how the Department's proposed regulation truly complies with it.

U. Punxsutawney Hunting Club, Inc. v. Pennsylvania Game Comm'n, No. 23 WAP 2023, 2026 WL 2111761 (Pa. July 21, 2026)

41. Does the Department obtain search warrants or other authorization from a court of competent jurisdiction in all cases prior to entering an individual's dwelling or other place where there is an expectation of privacy? If not, under what circumstances does the Department obtain a search warrant or other court authorization?

42. What evidence does the Department produce to show probable cause for justification in entering an individual's dwelling or another place where there is an expectation of privacy?

43. If the Department does not seek a search warrant or other court authorization, what exception to a warrantless search does the Department invoke to enter an individual's dwelling or another place where there is an expectation of privacy?

While the above listed case addressed whether officers of the Pennsylvania Game Commission were authorized to enter posted private land without a warrant under the open fields' doctrine, it nonetheless highlights the limits of a state agency through a constitutional lens. In that case, the

Pennsylvania Supreme Court held that Article I, Section 8 of the Pennsylvania Constitution provided more robust protection than the Fourth Amendment as it relates to the open fields of any landowner who has demonstrated a reasonable expectation of privacy by taking sufficient steps to exclude intruders therefrom. Accordingly, a warrant must be obtained based upon probable cause, or the officers must satisfy one of the recognized exceptions to the warrant requirement before entering such property. *Punxsutawney Hunting Club, Inc. v. Pennsylvania Game Comm'n*, No. 23 WAP 2023, 2026 WL 2111761, (Pa. July 21, 2026). We are requesting more information on how the Department's proposal complies with constitutional guarantees of privacy and this judicial opinion.

V. Request for a Crosswalk Document

In the regulatory package, the Department has identified several statutes that it argues provide the Department with both general and specific statutory authority to implement this regulation. However, sections of these statutes are not cross-referenced to specific sections of the regulation. To assist the Commission and interested parties in determining if the regulation is consistent with the intent of the General Assembly, we request that the Commission order the Department to identify specific sections of the cited statutes that correlate to specific sections of the regulation rather than simply reference statutes generally, which occurs in the proposed regulation.

W. Conclusion

The Department's proposed regulation is unprecedented. This proposal seeks to give the Department unfettered power to enter private residences, schools, and essentially any other location it deems necessary, all without a warrant or adequate probable cause. Law enforcement does not possess this type of authority, yet the Department is determined to grant such authority upon itself. The regulation seeks to limit the rights of parents to determine what they believe is best for their own children. In essence, the Department is saying that it knows best, and the citizenry of this Commonwealth needs to accept that without questioning the Department's actions.

To be clear, the Executive Branch (including the Department) was dealt a significant blow to its purported authority on two occasions in 2021 when the Pennsylvania Supreme Court limited its ability to make unilateral decisions during the pandemic and when the voters of this Commonwealth limited the Governor's authority under a disaster declaration. The Department has taken one line from the Court's decision and has crafted a 502-page manifesto that is a wish list for an overzealous agency that wishes to place the heavy hand of government on its citizens.

The Department is now seeking to restore the authority that the Court and the voters have limited under the guise of protecting the health of the citizens of this Commonwealth.

In its desire to bring the heavy hand of government down upon its citizens, the Department eviscerates long-recognized exemptions for medical, religious, and philosophical objections. Based on its proposals for susceptibility, the Department will essentially force our citizens to carry vaccine cards with them to prove that they don't meet the factors for susceptibility. It is becoming more apparent that the Department is seeking a mandatory centralized vaccine database so that it can check the vaccine status of an individual for a myriad of reasons, including whether they are susceptible to a certain disease or not.

We do not dispute the Department's authority to promulgate reasonable regulations for disease control measures. But it must do so under its statutory authority and pursuant to the requirements of the Regulatory Review Act. At minimum, the Department needs to substantially revise the regulation prior to issuing a final-form regulation. The better and more sound option is for the Department to withdraw this regulation and draft a regulatory package that does not seek to impose its will on the citizens of this Commonwealth. In doing so, the Department should engage with the General Assembly and not limit input to certain stakeholders as it looks to issue a new proposed regulation.

One of the factors the Commission must weigh in determining whether a regulation is in the public interest is whether the regulation represents a policy decision of such a substantial nature that it requires legislative review. Given what occurred in this Commonwealth several years ago during the pandemic, the court decision and the constitutional amendments that followed, and this proposal which seeks unprecedented authority by the Department, we assert that this regulation is substantial and requires legislative review.

In response to some of the criticism regarding its proposal, the Department issued the following statement:

> *Any misconstruing of these proposed changes designed to scare Pennsylvanians is inaccurate and disingenuous. Several years ago, the Pennsylvania Department of Health (DOH) transparently began the process to update a 25-year-old regulation that needs to be modernized to better support evolving public health needs and manage dangerous diseases; for example, allowing information to be submitted online, removing duplicative reporting requirements for certain professions, and making simple formatting changes to improve readability and reduce confusion about reportable diseases, infections, and conditions.*

> *Like most regulations in Pennsylvania, the Department's proposed changes to Chapter 27 are undergoing a comprehensive review process as required by law prior to going into effect — and DOH communicated with the Legislature on these proposed changes and process prior to posting for public comment. We encourage Pennsylvanians to review the proposed regulations for themselves and participate in the regulatory process by providing feedback during the extended public comment period. The public comment period for the proposed regulations runs through September 21, 2026. DOH values and recognizes the importance of feedback from the public and welcomes comments from the public during this time. Pennsylvanians can submit comments on the proposed regulations via e-mail to the Pennsylvania Department of Health at RA-DHCHAPTR27PROPREG@pa.gov.*[8]

We simply point out that there is no misconstruing of the facts. The concerns we have made in this comment letter are taken straight from the regulatory package. To make it even more apparent, we have taken the additional step of citing page numbers where the regulatory concern is located. To be fair to the process, we even ask questions in this letter where we are unsure of what the Department is proposing so that we can better understand the proposal. We are not misconstruing facts. We have read the regulatory package, we have substantial concerns, and we are now taking part in the comment process as set forth in law. The public is participating in this process as well. As of the date of this letter, there have been over 4,000 comments submitted with an overwhelming majority of those comments requesting that this regulation either be withdrawn, revised, or disapproved.

Regarding the Department's statement about transparency in this process and its communication to the General Assembly, we do agree that the Department served the regulatory package on the standing committees as required by law. However, at least as far as our legislative caucus is concerned, we were not invited to discuss this proposal over the last two years as the Department was conducting stakeholder meetings. We were not given a chance to weigh in or make suggestions prior to the proposal being published as stakeholder groups were able to do. So, while the General Assembly was served with the regulatory package as required by law, it must be pointed out that this publication is the first time we have been given a chance to weigh in on this proposal.

Let us be clear. This is not an argument about an individual being pro-vaccine or anti-vaccine. If a parent decides that it is in their child's best interest to receive a vaccine, they should be afforded that opportunity. Likewise, if a parent decides that they do not want to vaccinate their child for medical, religious, or philosophical reasons, that choice should be honored and not questioned.

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[8] https://www.abc27.com/pennsylvania/pennsylvania-department-of-health-attempts-to-expand-power-around-communicable-diseases/. Accessed on September 1, 2026.

Our comments are not about vaccines themselves. Rather, these comments are about the heavy-handed nature of what the Department is proposing, the limitations the Department is proposing regarding privacy and parental rights, and an overall questioning of whether this regulatory package is in the best interests of the Commonwealth under the Department's statutory authority to promulgate this regulation.

In 2022, when asked about some of the mandates that were imposed in the Commonwealth during the pandemic, our current Governor, who was the Attorney General at that time and a candidate for Governor, said the following:

> "This is an area where I think folks got it wrong," Shapiro said of school and business shutdowns. On mask and vaccine mandates, Shapiro said he opposed them and instead talked about a need to "educate and empower" the public, business owners, school leaders and others to protect themselves and others.
>
> "And to me, that's the approach we need to take more broadly as a public, which is to educate, empower and respect people's personal decisions and respect their personal freedom to make those choices," Shapiro told The Associated Press in an interview.[9]

We will end our comment letter with some rhetorical questions.

What changed from 2022 to the present:

- *Regarding opposition to mask and vaccine mandates?*
- *Where education and empowerment have been cast aside?*
- *With respecting people's personal decisions?*
- *With respecting people's personal freedom to make those choices?*
- *To bring about this proposed regulation that is the antithesis of this statement made just four years ago?*

Sincerely,

Kathy L. Rapp
65th Legislative District

Jesse Topper
78th Legislative District

[9] https://whyy.org/articles/josh-shapiro-pa-governor-race-wolf-covid-measures/. Accessed on August 26, 2026.

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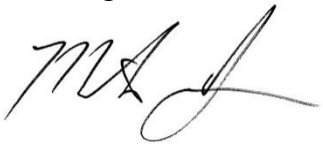

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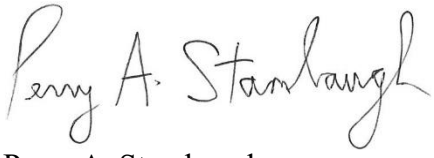

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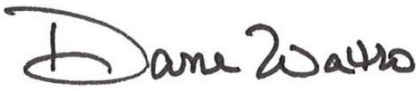

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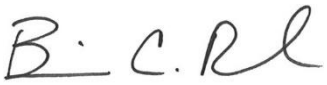

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cc: The Honorable Dan Frankel, Majority Chair, House Health Committee
The Honorable Michele Brooks, Majority Chair, Senate Health & Human Services Committee
The Honorable Art Haywood, Minority Chair, Senate Health & Human Services Committee
The Honorable Kim L. Ward, President Pro Tempore, PA Senate
The Honorable Joseph A. Pittman, Majority Leader, PA Senate
The Honorable Scott Martin, Majority Appropriations Chair, PA Senate
The Honorable David W. Sunday, Jr., Attorney General, Commonwealth of Pennsylvania