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Via Electronic Mail

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Re: Regulation No. 10-242 (relating to Communicable and Noncommunicable Diseases, at 28 Pa. Code Chapter 27)

Dear Dr. Bogen and Mr. Sumner:

Independence Law Center is a civil rights law firm that routinely handles cases involving human rights and liberties guaranteed by the First Amendment. We appreciate the opportunity to submit comments to the Pennsylvania Department of Human Services (the Department) on the proposed rulemaking.

The context of these proposed regulations is significant. On page 3 of the Regulatory Analysis Form, the Department acknowledges the Pennsylvania Supreme Court's decision in *Corman v. Acting Secretary of Pennsylvania Department of Health,* striking the Department's school-wide masking mandate and ruling that the Commonwealth's powers were limited by its regulations. The Department states that "the foregoing decision influenced the Department's proposed amendments to § 27.60(a), which would 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." (Regulatory Analysis Form, §9). Openly acknowledging the Court's holding that "the Department lacked the power" to issue the mask mandate, the Department proposes a massive overhaul of its regulations to grant itself sweeping powers that will impact virtually every citizen within this Commonwealth.

Considering the overwhelming negative and injurious impact of the government's COVID-era "lockdown" measures on adults, children, businesses, schools, churches, social gatherings, events, and virtually every aspect of life in Pennsylvania, this justification is very disturbing. Even more disturbing is the Department's disregard for the will of the people, which was demonstrated clearly and unambiguously when

voters passed two constitutional amendments limiting the governor's emergency powers. Going far beyond the measures that the public experienced during COVID and rejected, the Department proposes to expand its powers to exponentially enlarge its scope of control outside of true health emergencies and impact the routine health care of virtually every citizen of this Commonwealth. The expansive powers of this proposed regulation raise grave concerns, many of which are discussed below:

I. The Department proposes over 500 pages of rulemaking and analysis without a shred of data in support of these sweeping changes.

In its opening paragraph of the Regulatory Analysis Form, the Department states that the proposed rulemaking contains "much needed amendments. . ." (Form, §7). With that introduction, one would reasonably expect the Department to present objective data to demonstrate this need. While consuming 502 pages to present the sweeping scope of this rulemaking, this need is never demonstrated. Shockingly, the Department acknowledges, on page 37 of the Regulatory Analysis Form, that it "did not rely on data as the basis for this regulation." (Form, §28). For this administration to grant itself such sweeping powers that will impact every Pennsylvania individual without offering any objective, quantifiable data that would suggest a "need" for these changes, is very concerning.

According to the Department, over 400,000 health care practitioners and over 6,000 health care facilities will be impacted. All 9,589 clinical laboratories will be impacted. All 500 school districts, more than 160 brick-and-mortar charter schools, 14 cyber charter schools, approximately 396 colleges, and 6,378 childcare group settings as well as the students and employees in those settings will be impacted. Approximately 3,200 veterinarians will also be impacted. Finally, the Department states that all 13 million individuals in this Commonwealth will be impacted. (Form, §10). And yet, the Department could not even make a token effort to offer data to demonstrate a need for these changes? Pennsylvanians deserve better from their government.

II. The Department admits many times throughout the proposed regulation that it cannot measure the financial, economic, and social impact on all those affected.

Repeatedly, throughout the proposed regulation, and particularly in section 17 of the Regulatory Analysis Form, the Department acknowledges that it has no way to estimate the financial, economic, and social costs to all those affected by these regulations. Using ambiguous phrases like "due to varying factors," "[the regulation] may result in…," "the Department does not have sufficient data," and "the Department is not able to estimate the specific effects of this amendment" in virtually every paragraph in which it supposedly assesses the impact of this regulation, the Department simply writes off any responsibility to assess real-life, measurable impacts. For the Department to exhibit such a dismissive posture and

lack of due diligence in matters of such vital importance to Pennsylvanians is troubling.

III. Section 27.1 of the proposed regulation contains new, expansive definitions and categories that are without limitation and could easily be misused under the color of state authority.

New definitions for words and phrases such as "*Condition*" (Annex A, p. 3), "*Emerging disease or condition*" (Annex A., p. 4), and "*Of public health significance*" (Annex A, p. 9) are open-ended and authorize state power in ways that go far beyond disease control.

"*Condition*," defined by the rulemaking as "[n]oninfectious medical ailment or other health-related event," is virtually limitless. When used as justification for the government to interfere in the lives of its citizens, the potential for abuse is great. Any symptom that can be associated with one of the reportable diseases, infections, or conditions would seemingly authorize government-mandated reporting, monitoring, surveillance and/or other control measures. Since many common cold and allergy symptoms can also appear for other conditions, almost any "ailment" or "health related event" could now be tracked and become justification for action by the Department.

"*Emerging disease or condition*" is equally open-ended and virtually limitless. It is defined as a "disease or condition that has been identified in **a** population for the first time, or that may have existed previously but is rapidly increasing in incidence in **a** geographic area or subset of the population" (emphasis added). Note that there is no language requiring that this disease or condition be identified in Pennsylvania or even the United States. The definition simply requires that some disease or "condition" be identified in a population or a geographic area, presumably somewhere in the world. Again, using this language as justification to exercise control over, or take action against Pennsylvania citizens is to grant the government unlimited power under this proposed regulation.

Finally, the phrase "*Of public health significance*" is unlimited. Defined as "[a] disease, infection or condition that can reasonably be expected to lead to adverse health effects in the community," this could be interpreted to include the common cold or any other "condition" which adversely affects people.

IV. The expanded surveillance capabilities detailed in section 27.1 infringe on the health care practitioner-patient privilege and violate individuals' rights to privacy and confidentiality in their health care decision-making and treatment.

Section 27.1 defines "*Surveillance*" as "[t]he ongoing, systematic collection, analysis

and interpretation of health-related data essential to planning, implementing and evaluation of public health practice." Through its "S*yndromic Surveillance System*," the proposed regulation would give the government virtually unlimited authority to track individual health care decisions and conditions without any requirement of necessity. Indeed, under the guise of "prevention," for any of the greatly expanded list of reportable diseases, infections, and conditions, the government can mandate access to virtually anyone's medical records. While the Health Insurance Portability and Accountability Act allows disclosures for the purpose of preventing and controlling disease, the addition of new, vague categories such as "condition," "emerging disease or condition," and "of public health significance" significantly enlarges the scope of data that would be collected on individuals. For the government to seek such power to track individuals in this way is extremely concerning.

V. Specifically, new section 27.4a's required reporting by hospital emergency departments of visit data for syndromic surveillance, without justification or limitation, is a violation of individual rights to privacy and health care practitioner-patient confidentiality.

Newly proposed section 27.4a appears to afford the Department unlimited access to every individual's extensive personal information upon entry to a hospital emergency room, regardless of whether that visit is for a broken finger or toe, a urinary tract infection, or a communicable disease. Why? For the Commonwealth to mandate this reporting and track and store this health care information for every person who has reason to request emergency room treatment for any reason is extremely troubling. On page 31 of the Regulatory Analysis Form, the Department states that "[a]ll hospitals are already voluntarily reporting this data to the Department." (Form, §22). If this is true, why are hospitals doing this? Has the state made this an "expectation" without legal authority? And even if it is true, for the Department to *mandate* this all-encompassing reporting for the purpose of its own surveillance is unsettling. It is quite possible that this kind of overreach will discourage individuals from seeking emergency medical care.

VI. The reporting and tracking of immunization delivery proposed in new section 27.36 is a violation of health care practitioner-patient confidentiality that most people presume and expect when they visit a health care provider.

This statewide tracking of individuals' immunization delivery will allow the Commonwealth to track and maintain health care data for every individual who has immunization contact with a health care provider. The provision allows for routine tracking that is not connected with any active health emergency. For the government to mandate this reporting and track this information through its surveillance system is particularly disturbing in light of the expansive control that the government is proposing to wield over individuals in Subchapter C, Disease Control Measures.

Furthermore, this kind of tracking goes far beyond the kind of "emergency" government intrusion that Pennsylvanians resoundingly rejected when they approved the two constitutional amendments to limit the governor's emergency powers.

It is important to note that a patient's ability to decline this reporting in writing is of no value, as there is no requirement that a health care provider or facility notify the patient of the mandated reporting or the right to decline. A person cannot effectively exercise a right where there is no knowledge of the right.

VII. The new categories of "prevention, containment or mitigation" in section 27.60 are virtually limitless in their scope of influence and control over the health care decisions of Pennsylvania citizens.

In section 27.60, the new categories of "prevention, containment or mitigation," and the addition of "condition" as justification for the Department to direct isolation of a person or "any other disease control measure the Department or the local health authority considers to be appropriate" allow for subjective and discretionary decision-making and, therefore, the potential for abuse.

The Department grants itself sweeping powers over Pennsylvania citizens' health care decisions and treatment. In particular, the addition of the word "prevention" is concerning. "Prevention," which the rulemaking does not even attempt to define or limit, anticipates something that has not yet occurred. At the same time the Department proposes to enlarge its scope of control with these amendments, it maintains its own subjective and discretionary authority to isolate and quarantine individuals or take "any other disease control measure the Department or the local health authority considers to be appropriate." Many of the actions authorized by this proposed regulation, including warrantless home entry and school entry, can be justified as "prevention" of a disease or condition that, if it exists at all, isn't a threat, or may never be a threat, to anyone. This expansive state power can be easily abused by the Department to manipulate individuals and any entity within the scope of its authority.

The addition of the ambiguous word "condition" to this section suggests a health status that does not rise to the level of disease or infection and yet, the Department adds it as justification for it to exercise, in its own discretion, the "control measures" of isolation, surveillance, segregation, and quarantine against Pennsylvania citizens. "Condition" is defined in section 27.1 as a "noninfectious medical ailment or other health-related event." Why would the Department propose to grant itself authority to take any of these actions against Pennsylvania citizens for a health-related event that is noninfectious and does not meet the definition of a disease?

The changes in this section go far beyond what most Pennsylvania citizens consider

reasonable disease control measures. Moreover, the potential for abuse here is highly disturbing.

VIII. In new section 27.60a, the Department grants itself sweeping powers to enter any home or building without obstruction—powers that are highly intrusive and apparent violations of the constitutional rights of individuals, parents, and religious schools.

The authority granted in this new section is different than that contained in existing section 27.152(b). Section 27.152(b) states that "[a] person may not interfere with or obstruct a representative of the Department or a local health authority who ***seeks to enter*** a house, health care facility, building or other premises to carry out an investigation of a case or outbreak, if the representative presents documentation to establish that he is an authorized representative of the Department or the local health authority." (emphasis added). This section does not contain the words "may enter" and does not authorize entry. Rather, in using the words "seeks to enter," section 27.152(b) presumes that the representative is seeking, or has obtained, legal authority to enter in the first place, either with consent of an owner or occupant, or a search warrant. After all, Americans have the protection of the 4th Amendment, which protects people from unreasonable searches and seizures by the government.

Under new section 27.60a, the Department grants itself sweeping authority to enter any home or building without any legal process or probable cause: "The Department or local health authority ***may enter*** an apartment, building, health care facility, school, college or university, or other location as necessary to conduct its investigation under this chapter. . ." (emphasis added). The Department bolsters its authority even more with subsection (c): "A person may not obstruct or interfere with the department or local health authority's investigation under the chapter." This provision is alarming when understood within the context of all the other added control measures and expansion of government power—particularly, the addition of the ambiguous words of "condition" and "prevention" throughout the proposed regulations. The scope of authority and control the government is seeking over the lives of its citizens is very disconcerting.

IX. New sections 27.60a, 27.60b, and 27.60c, which give the Department broad, unobstructed power over school students during school hours, are a blatant violation of the constitutional rights of parents to direct the upbringing of their children.

In addition to granting itself the authority to demand entry into any school, including private and religious schools, for virtually any reason relating to its "investigation," the Department specifically prohibits interference by anyone, including parents, with the Department's access to any student, no matter the age. This proposed authority over children is highly intrusive and a clear violation of the constitutional rights of

parents to be involved in matters concerning their children. The United States Supreme Court has spoken very clearly on the rights and role of parents in the lives of their children. "The liberty interest at issue—the interests of the parents in the care, custody and control of their own children—is perhaps the oldest of the fundamental liberty interests recognized by the Court." *Troxel v. Granville*, 530 U.S. 57, 65 (2000). Parents have the fundamental right to make decisions concerning the care of their children. *Id.* at 68-69. This includes any discussions or considerations relating to their health. Pennsylvania courts also recognize the primary role of parents in the upbringing of their children. *Gruenke v. Seip*, 225 F.3d 290, 307 (3d Cir. 1999). For the Department to mandate that schools grant its representatives unfettered and unquestioned access to students, regardless of their age and without parental involvement or even notification, is extremely disturbing.

Under this new section and the sweeping powers of this proposed regulation, there is nothing to prohibit a representative of the Department from meeting with elementary school students, with the stated purpose of preventing disease, to discuss vaccination status or even sexually transmitted diseases with them. Furthermore, the broad authority granted by this section would allow the Department to introduce any child to "partner services," which is defined by this regulation to include vaccination and the "reproductive health services" of contraception and abortion, all outside of any parental involvement.

Additionally, forcing religious schools to allow access by Department officials to students is likely to invoke unconstitutional entanglement with religious liberties. Many religious schools maintain religious beliefs against abortion or other categories of "partner services." Consequently, a government regulation requiring schools to act in violation of their religious beliefs would violate the schools' First Amendment/ Free-Exercise-of-Religion rights.

This new grant of unobstructed authority for the Department to access students without parental consent also violates Pennsylvania law. Under the Minors' Consent Act, 35 P.S. §10101, parents and guardians in Pennsylvania have the legal authority and duty to make decisions regarding medical care for children under 18. The Department cites 35 P.S. §10103 as its authority for meeting with children privately and without parental knowledge or consent. However, section 10103 allows minors to consent for specific services and treatment; it does not authorize government officials to act proactively and secretly to discuss medical matters with minors in the broad context proposed by the Department. The grant of authority and powers contained in these new sections go far beyond the scope of section 10103.

These provisions, in their totality, trample the constitutional rights of parents and religious schools. Again, for our government to seek this kind of control over its citizens is quite troubling.

X. Sections 27.60b, 27.60d, and 27.60e, which give the Department broad, unobstructed power over health care facilities and medical records, will violate the constitutional rights of religious health care facilities.

The mandate for all health care facilities, including religious health care practices and pro-life pregnancy centers, to provide the Department or local health authority with reasonable and timely access to a person for the purpose of providing "partner services" is unconstitutional. Health care facilities have the right not to participate in services that are inconsistent with their religious beliefs. Abortion is a service that many health care providers do not offer and will not discuss with their patients. To require such facilities to "provide reasonable and timely access" to their patients so that the Department may introduce the patient to "partner services," including abortion, violates the First Amendment rights of religious health care organizations.

The United States Supreme Court has held that government cannot compel a religious organization (including religious schools and health care entities) to disseminate a message that is contrary to its religious mission and beliefs. In *Nat'l Inst. of Family & Life Advocates v. Becerra*, 585 U.S. 755 (2018), the Court held that pregnancy centers were protected against compelled speech promoting abortion services. The Constitution guarantees religious organizations "independence from secular control or manipulation" in matters of faith and doctrine. *Kedroff v. St. Nicholas Cathedral of Russian Orthodox Church*, 344 U.S. 94, 116 (1952). Compelling a religious organization to convey a message that violates its religious beliefs violates the organization's First Amendment rights.

XI. Section 27.60e gives the Department expansive access to the private medical records of individuals without any regard for individual health care practitioner-patient privacy or confidentiality.

Under the expansive scope of this regulation, the Department grants itself access to patient medical records for just about any purpose, as long as it claims it is "conducting an investigation." Again, with the expansive powers afforded by such broad terms as "prevention" and "condition," its powers are virtually unlimited. The Department goes a step further to state that a "person may not obstruct or interfere with the review of patient medical records by the Department or local health authority." In other words, an individual's' desire for privacy in their medical records and decision-making is of no consideration. That the Department mandates this expansive access without any conditions other than for the purpose of "investigation" is just another troubling piece of these proposed new powers over the citizens of this Commonwealth.

XII. The erasure of "women" and "mother" throughout the regulation in favor of "pregnant individual" is offensive and clearly designed to pander to special interests and further a political agenda.

Only women can become pregnant and deliver babies. Until recently, with the emergence of gender identity ideology, that was a biological and anatomical reality that was never questioned. For the Department of Health to delete any reference to women and mothers in favor of terminology that endorses and promotes an ideology over reality ignores the priority of health and the biological realities that must be recognized when delivering good health care.

Conclusion

The expansive powers proposed by this rulemaking are highly intrusive and, in some instances, a violation of constitutional rights. With recent memories of COVID-era government control, Pennsylvania citizens do not want their government to have this kind of expansive control and oversight over their health care systems and their own medical decision-making. If these proposed regulations go into effect, they will likely have a chilling effect on the willingness of individuals to seek services from health care providers.

Respectfully submitted,

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