The Pennsylvania Small Enterprise Foundation

PA Family
Protect Life. Promote Family. Preserve Freedom.

September 18, 2026

ATTN: Pennsylvania Department of Health; Pennsylvania Independent Regulatory Review Commission

RE: Public Comment on Proposed Changes to 28 Pa. Code Chapter 27, Communicable and Noncommunicable Diseases (Regulation No. 10-242; IRRC No. 3490)

Dear Secretary Bogen, Chairman Bedwick, and associates,

The Pennsylvania Small Enterprise Foundation (PSEF) exists to promote the preservation and growth of small enterprise by helping small businesses and other small enterprises (such as churches and community organizations) engage with government. Our goal is to make it easier for these organizations to start, grow, and prosper. Inclusive in this mission is regulatory advocacy. Likewise, the mission of the Pennsylvania Family Institute is to strengthen families in Pennsylvania by restoring to public life the traditional, foundational principles and values essential for the well-being of society, including limited government and freedom of choice.

The cost of health care in Pennsylvania (and the United States as a whole) has increased dramatically over the past 20 years, placing significant strains on families, employers and public budgets.[1] A significant portion of these costs relate to the administrative and regulatory environment rather than to the delivery of care.[2]

Therefore, PSEF and the Pennsylvania Family Institute ("the Commenters") appreciate this opportunity to provide comment on the proposed amendments to 28 Pa. Code Chapter 27, relating to communicable and noncommunicable diseases (IRRC Regulation No. 3490), and we thank the Pennsylvania Department of Health (the "Department"), the State Advisory Health Board, and the Independent Regulatory Review Commission (the

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[1] See Irene Papanicolas, Liana R. Woskie, and Ashish K. Jha, "Health Care Spending in the United States and Other High-Income Countries," *Journal of the American Medical Association* 319, no. 10 (2018): 1024–1039; Centers for Medicare and Medicaid Services, Office of the Actuary, *National Health Expenditure Accounts: Health Expenditures by State of Residence, 1991–2020* (Baltimore: CMS, 2022), Pennsylvania.

[2] See for example Phillip Tseng et al., "Administrative Costs Associated With Physician Billing and Insurance-Related Activities at an Academic Health Care System," *Journal of the American Medical Association* 319, no. 7 (2018): 691–697; Nikhil R. Sahni, Brandon Carrus, and David M. Cutler, "Administrative Simplification and the Potential for Saving a Quarter-Trillion Dollars in Health Care," *Journal of the American Medical Association* 326, no. 17 (2021): 1677–1678; Lawrence P. Casalino et al., "What Does It Cost Physician Practices to Interact with Health Insurance Plans?" *Health Affairs* 28, no. 4 (2009): w533–w543.

“Commission”) for their consideration of our input. We hope to contribute to the Department's and the Commission’s understanding of the economic impacts of this proposed regulatory action and the impact of public health reporting and control regulation more broadly, with the confidence that this analysis will be useful in deliberations over the form and estimated impact of this final rule and for other actions in the future.

The Department's stated objectives in this rulemaking are laudable and important: to update regulations in order to “ensure the overall public health and safety by reducing the risk and spread of diseases, infections and conditions.” The Commenters share these goals, and provide this comment with the purpose of contributing to the Department's and the Commission's assessment of the potential costs associated with certain elements of this proposal so that they can be weighed carefully against the expected benefits.

Some of the proposed changes represent simplifications or modernization of standards that present no immediate costs, and may offer tangible benefits. However, there are a significant number of new requirements (some of which the Department has already acknowledged in its partial cost-benefit analysis) that will likely create significant new costs for families, schools, childcare providers, and healthcare providers, and also represent a significant expansion of state power into the lives of private citizens. While the Department may have statutory authority to promulgate regulations intended to implement state law, it does not have the authority to do so in an arbitrary, unreasoned fashion. The Commenters will argue here that many elements of this proposal threaten to create significant new costs for the above-mentioned parties without meaningful benefits to public health and safety, and the Department has not yet taken the proper procedural steps to weigh these tradeoffs.

Our response consists of several sections, which proceed as follows: First, we describe the results of an attached independent analysis, which illustrates the significant incremental costs created by this proposal, almost none of which were considered in the Department’s analysis and which are likely to exceed $100 million annually. Next, we discuss and quantify several alternative policies that the Department could have considered, which would accomplish the same goals with significantly less cost. Lastly, we discuss several considerations for both the Commission and the Department, which highlight the extent to which this proposal violates procedural norms for regulatory rulemaking in Pennsylvania, and may even violate Pennsylvania law.

1. The Department's Regulatory Analysis Omits the Principal Costs of the Proposed Rule

The Department's Regulatory Analysis Form ("RAF") reports a cost to the regulated community of $0 in each of the six fiscal years it covers.[3] It reaches that figure by a repeated formula: in nine separate places the Department concedes that a provision will impose costs on practitioners, facilities, laboratories, schools, child care providers or individuals, states that it lacks the data to quantify them, and records the result as "no overall fiscal impact."[4] The Department further states that it "did not rely on data as the basis for this regulation" and that each of the five small-business flexibility methods the Regulatory Review Act directs it to consider was "not considered."[5] The Commenters have undertaken the analysis the Department did not. Using the Department's own counts of regulated parties, its own published surveillance and vital statistics, and Bureau of Labor Statistics wage data, the Commenters estimate that the provisions the Department scored at zero or omitted impose approximately $8.7 million per year in recurring costs on the private regulated community, $8.4 million per year on school districts and other political subdivisions, and a further $89.3 million per year on private individuals (parents, pregnant patients and their insurers), for a total of approximately $106 million per year, plus $11.9 million in one-time implementation costs, offset by roughly $0.6 million in annual savings. The full analysis, including the derivation of each unit cost and the source for every figure, appears in Appendix Tables 1 through 3.[6]

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[3]Pennsylvania Department of Health, Regulatory Analysis Form: Communicable and Noncommunicable Diseases, 28 Pa. Code Chapter 27 (Proposed Rulemaking, IRRC No. 3490, June 4, 2026), Independent Regulatory Review Commission, https://irrc.state.pa.us/docs/3490/AGENCY/3490PRO.pdf, Question 23. The same table reports costs to state government rising from $384,903 in FY2026-27 to $2,111,716 in FY2030-31, almost entirely for the new birth defects registry, and $0 to local government.

[4]Id., Questions 15 and 19 (§§ 27.21a, 27.22, 27.33a, 27.36, 27.37, 27.60c, 27.71a and 27.99a–b); Question 13 (§ 27.72). Representative language: practitioners and facilities that report manually "will need to allocate additional resources, including staff time"; non-reporting vaccine providers "will need to establish a process for reporting, which may require additional staff or IT support"; schools and child care settings "may also be financially impacted by an increase in staff and student absences"; individuals will bear "a financial impact due to individuals missing time from work or school." Each is followed by a conclusion of no fiscal impact.

[5]Id., Questions 28 and 27.

[6]See Appendix Table 1 (aggregate costs by requirement), Appendix Table 2 (derivation of each cost per party or instance) and Appendix Table 3 (Department figures with which PSEF disagrees). Where a volume rests on a PSEF assumption rather than a Department, Census or federal statistical source, Appendix Table 1's notes state the assumption and give the row total at alternative values; across those alternatives the recurring total ranges from approximately $64 million to $214 million per year (the low case reduces the assumed exclusion increases to 5 percent for schools and 10 percent for child care, halves the assumed manual-reporting share for new PA-NEDSS and laboratory reports (the PIERS row is not toggled), and uses the Department's own birth-defect count; the high case doubles the exclusion increases, counts all mandated prenatal tests, treats all new reports as manual, uses CDC birth-defect prevalence, and reads § 27.60d to require verbal notice with every result).

The largest costs arise from the exclusion provisions, which the Department discusses at length and costs at nothing. Proposed § 27.71a adds eighteen conditions to the school and child care exclusion chart and, for the first time, excludes close contacts of cases; proposed § 27.72 lowers the fever threshold for exclusion from 102°F to 100.4°F and revises the symptom list. The Department concedes these changes will produce "more frequent exclusion of children" and "an increase in staff and student absences" requiring substitute teachers.[7] Applying national illness-absence rates to Pennsylvania's 1.98 million school-age children and 350,000 children in licensed child care, and assuming the new rules increase exclusion-days by 10 percent in both schools and child care, the Commenters estimate $65 million per year in costs from § 27.71a and $19 million from § 27.72. We consider this estimate of 10 percent to be conservative given the number of new exclusions conditions added by the rule, and at 20 percent the rule would add $168 million in cost.[8] Roughly $73 million of that total is parents' lost wages, counted only for children young enough to require a parent at home and valued at the Pennsylvania mean hourly wage; the remainder is substitute teachers, replacement child care staff, and school nurse time. The Commenters acknowledge some uncertainty around these estimates because the Commonwealth publishes no illness-absence or exclusion data. However, they are also the figures the Department was best positioned to estimate, since it identified the mechanism and administers the school health reporting system that would quantify it. It is also worth noting that while some parents may have the luxury of available parental leave from their employer, this merely transfers the cost from one party to another, and threatens to impose millions in additional costs on Pennsylvania employers.

The prenatal testing mandates are the clearest example of an analysis abandoned midstream. Proposed §§ 27.99a and 27.99b require a hepatitis C test and two HIV tests for every pregnancy in the Commonwealth. The Department cites Quest Diagnostics list prices of $62, $85 and $282 and patient co-payments of $25 to $30, then concludes it is "estimating no fiscal cost."[9] The Department's own Bureau of Health Statistics reported 158,798 pregnancies to Pennsylvania residents in 2024.[10] Multiplying the Department's prices by the Department's pregnancy count, and counting only tests not already performed under existing CDC guidance, yields $16.4 million per year in incremental test

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[7]Department of Health, Regulatory Analysis Form: Communicable and Noncommunicable Diseases, 28 Pa. Code Chapter 27 (Proposed Rulemaking, IRRC No. 3490, June 4, 2026), Independent Regulatory Review Commission, https://irrc.state.pa.us/docs/3490/AGENCY/3490PRO.pdf, Questions 13 and 19.

[8]See Appendix Table 1, §§ 27.71a and 27.72, and notes. Baseline absence is the National Health Interview Survey distribution of school days missed for illness or injury (2.9 days per child per year) applied to the Department's own EDDIE population denominators and to licensed child care capacity reported by the Office of Child Development and Early Learning. Baseline model assumption is 10 percent; at half and double those values the two provisions together range from $42 million to $168 million per year.

[9]Department of Health, Regulatory Analysis Form, Question 19.

[10]Pennsylvania Department of Health, Bureau of Health Statistics and Registries, Pennsylvania Vital Statistics 2024: Reported Pregnancies, Table E-1 (Harrisburg: Department of Health, 2026).

charges to patients and insurers and $1.1 million in nursing time for ordering and result review, or $17.5 million in total; if every mandated test were counted, test charges alone would be $37 million.[11]

The reporting mandates are individually smaller but rest on volumes the Department already publishes. The treatment-reporting requirement in § 27.33a requires a second report on every tuberculosis and sexually transmitted disease case; the Department's own EDDIE surveillance system records an average of 74,450 such cases per year, which at fifteen minutes each is $1.2 million annually.[12] The PIERS immunization mandate in § 27.36 falls on the 4,750 providers the Department itself identifies as not currently reporting; the Commenters estimate $2.3 million per year in manual dose entry and $2.5 million in one-time interface costs.[13] The expanded reportable lists in §§ 27.21a and 27.22 require every one of the Department's 400,000 practitioners and 6,000 facilities to learn a list that has more than doubled, at a one-time cost the Commenters estimate at $7.4 million, and require laboratories and ordering providers to capture and transmit patient employer and pregnancy status on at least 94,000 reportable results per year, at $663,000 annually.[14] The mandatory emergency department data feed in § 27.4a, which the preamble says will have "no impact on hospitals," authorizes the Department to require "other data elements deemed necessary" without limit; the Commenters estimate the maintenance burden alone at $262,000 per year and note that the open-ended clause makes the true cost unbounded.[15]

Nowhere is the absence of analysis more consequential than in proposed § 27.60. In 2021 the Supreme Court of Pennsylvania held that the Department's school masking order exceeded its authority, resting its decision in part on the fact that the existing § 27.60 permits the Department to impose other disease control measures only for purposes of surveillance.[16] The Department now proposes to add "prevention, containment or

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[11]Appendix Table 1, §§ 27.99a and 27.99b, and notes. First-trimester HIV screening is treated as existing standard of care with no incremental cost. CDC recommends third-trimester repeat testing only in high-prevalence settings, so the universal third-trimester test is treated as 85 percent incremental; hepatitis C screening is treated as 50 percent incremental; the 50 percent current-uptake figure is a PSEF assumption.

[12]Pennsylvania Department of Health, Bureau of Communicable Diseases, "Sexually Transmitted Diseases, 2021–2023" and "Communicable Diseases, 2021–2023," Enterprise Data Dissemination Informatics Exchange (EDDIE), accessed September 2026; Appendix Table 1, § 27.33a.

[13]Appendix Table 1, § 27.36, and notes.

[14]Appendix Table 1, §§ 27.21a and 27.22, and notes. The employer and pregnancy fields are not part of current laboratory workflow and must be obtained from the ordering provider for every reportable result, whether reported electronically or manually. The 94,000 figure counts only conditions for which the Department publishes case counts and is a floor; the unit cost combines laboratory staff time to request the fields with ordering-provider staff time to supply them.

[15]Appendix Table 1, § 27.4a. The Department's own Question 12 concedes that emergency department reporting is currently voluntary, which is difficult to reconcile with the preamble's statement that a mandate will have no impact.

[16] Corman v. Acting Secretary of the Pennsylvania Department of Health, 266 A.3d 452 (Pa. 2021).

mitigation" to that section, supplying the authority the Court found lacking, and its Regulatory Analysis Form explicitly cites the Court's decision as the reason for the change.[17] For a provision that would reach every resident, business, school and property owner in the Commonwealth, the RAF identifies no cost, considers no alternative, and states that the Department "is not able to specifically estimate the effects."[18]

Several of the Department's statements are not merely unquantified but contradicted by information in the Department's possession or in free public sources. The Department states it "does not have sufficient data to determine the number" of small physician practices, laboratories, home health agencies, child care providers or veterinary offices it regulates; the Census Bureau published those counts for Pennsylvania in April 2025, fourteen months before the RAF was filed, and they show that the overwhelming majority of firms in each category are small businesses.[19] The Department states it lacks data to estimate the provider cost of birth defects reporting; its own EDDIE system publishes birth-certificate counts of major anomalies, averaging 418 per year, which together with CDC prevalence data bracket the reporting volume.[20] It concedes that eliminating duplicate veterinary reporting "may result in a cost savings" and records the savings as zero. It describes neonatal abstinence syndrome reporting as voluntary, while its own annual surveillance report states that all hospitals have been required to report since 2020 and that 78 of the 86 hospitals with reporting capability in its surveillance system did so for 2022.[21] And it states it relied on no data for a regulation whose case counts, birth counts, population denominators and provider counts it publishes itself. Appendix Table 3 sets out each Department figure or statement that the Commenters' analysis contradicts, the independent figure, and its source.

2. Less Burdensome Alternatives the Department Did Not Consider

The Regulatory Review Act requires the Department to describe the alternatives it considered and rejected and to state that the least burdensome acceptable alternative has

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[17] Department of Health, Regulatory Analysis Form, Question 9

[18] *Id., Question 15*.

[19] U.S. Census Bureau, Statistics of U.S. Businesses 2022: U.S. and States, 6-digit NAICS, Enterprise Employment Size (April 10, 2025), Pennsylvania: offices of physicians 3,089 of 3,180 firms under 500 employees; offices of dentists 4,155 of 4,172; medical laboratories 117 of 138; home health agencies 860 of 937; child care services 2,859 of 2,885; veterinary services 992 of 1,010. See Appendix Table 3.

[20] Pennsylvania Department of Health, "Birth Defects, 2020–2024," Pennsylvania Birth Certificate Dataset, EDDIE; Appendix Table 1, § 27.37, and notes.

[21] Department of Health, Regulatory Analysis Form, Question 12 ("Pennsylvania does currently receive this information from hospitals and birthing centers but relies on voluntary reporting"); Pennsylvania Department of Health, Bureau of Family Health and Bureau of Epidemiology, Neonatal Abstinence Syndrome: 2022 Report (Harrisburg: Department of Health, September 2024), 6, 23 ("Effective January 1, 2020, all hospitals in Pennsylvania are required to report NAS cases"; "Of the 86 active hospitals with iCMS reporting capabilities in 2022, 78 (91%) reported cases"). The Department received 1,254 case reports for 2022 through its Internet Case Management System.

been selected.[22] The RAF lists four alternatives, all suggested by stakeholders. Three were requests to make the regulation more stringent, which the Department declined; the fourth was a request to preserve the existing incorporation by reference in § 27.77, which the Department rejected on legal grounds.[23] The Department identified no less burdensome alternative of its own for any of the provisions that account for the costs in Part 1. Several were readily available and would have achieved the Department's stated objectives at a fraction of the cost. These are summarized below:

Exclusion (§§ 27.71a and 27.72). The Department cites the American Academy of Pediatrics as the basis for the new fever threshold, but the AAP's own guidance on exclusion from child care and school does not treat a temperature alone as grounds for exclusion; it requires fever accompanied by behavior change or other signs of illness.[24] Adopting the AAP exclusion standard the Department already cites, rather than a bare temperature, would eliminate most of the $19 million annual cost of § 27.72. Limiting close-contact exclusion under § 27.71a to the small number of conditions for which contact exclusion has demonstrated public health value, such as measles and pertussis, rather than applying it across the chart, would remove a large share of the $65 million attributed to that section; each percentage point of avoided increase in exclusion-days is worth approximately $6.5 million per year.[25]

Prenatal testing (§§ 27.99a and 27.99b). CDC recommends repeat third-trimester HIV testing only in high-prevalence jurisdictions and for patients with identified risk.[26] Confining the third-trimester requirement to the counties CDC's criteria identify, rather than mandating it statewide, would avoid most of the $12.2 million annual cost of § 27.99b while capturing the population the recommendation targets. Because CDC and ACOG already recommend universal hepatitis C screening in pregnancy, the Department could achieve the same clinical result through guidance to obstetric providers and payers rather than a regulatory mandate that reaches every pregnancy and every objecting patient in the Commonwealth.

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[22]71 P.S. § 745.5(a)(12).

[23]Department of Health, Regulatory Analysis Form, Question 26 (mandatory child care reporting; a shorter immunization-reporting deadline; adding pinworm to the exclusion chart; retaining the ACIP incorporation by reference).

[24]American Academy of Pediatrics, Managing Infectious Diseases in Child Care and Schools, 6th ed. (Itasca, IL: AAP, 2023), "Conditions Requiring Temporary Exclusion." The Department cites this reference for the exclusion chart in § 27.71a but adopts a bare temperature standard in § 27.72.

[25]Appendix Table 1, § 27.71a, and notes. Existing Department of Human Services regulations at 55 Pa. Code Chapter 3270 already govern exclusion of ill children from child care; harmonizing rather than layering the two standards is itself a less burdensome alternative.

[26]Bernard M. Branson et al., "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings," MMWR Recommendations and Reports 55, no. RR-14 (2006): 1–17.

Reporting (§§ 27.21a, 27.22, 27.33a, 27.36, 27.60d). Five alternatives track the methods the Regulatory Review Act directs the Department to consider for small businesses.[27] First, limit the treatment-reporting requirement in § 27.33a to syphilis and tuberculosis, the conditions for which the Department conducts treatment follow-up, rather than chlamydia and gonorrhea, which account for 73,000 of the 74,450 annual cases and roughly $1.17 million of the $1.19 million cost. Second, exempt providers administering fewer than a threshold number of doses per year from the PIERS mandate in § 27.36, or extend the 30-day deadline to allow monthly batch submission; the manual-entry cost of $2.3 million per year falls almost entirely on small practices, independent pharmacies and nursing homes without electronic interfaces. Third, drop the employer and pregnancy-status fields from § 27.22 except for conditions with occupational or perinatal significance, avoiding $663,000 per year in laboratory and provider time on every reportable result. Fourth, for the newly reportable conditions in §§ 27.21a and 27.22, require reporting only through electronic laboratory and case reporting where it exists, and confine manual reporting to conditions that trigger a public health response, excluding common respiratory viruses such as rhinovirus and adenovirus that do not. Fifth, state in § 27.60d that a standard written statement in result letters and portal messages satisfies the partner-services notice, and limit it to positive results, the only circumstance in which partner services apply; as written the notice attaches to every negative screening result and, if read to require an individual verbal notice, would cost roughly $1.6 million per year rather than a one-time template change of under $300,000.

Registries and timing (§§ 27.37, 27.4a, 27.21a). The Department could build the birth defects registry on passive surveillance from the birth-certificate data it already collects in EDDIE and hospital discharge data held by the Pennsylvania Health Care Cost Containment Council, adding active provider reporting only for anomalies those sources miss; that approach would reduce both the provider cost in Appendix Table 1 and the Department's own $1.5 to $2.1 million annual cost. The open-ended “other data elements” clause in § 27.4a could be replaced with a defined element list changeable only by regulation, restoring a cost the current text makes impossible to estimate. And a twelve-month delayed effective date for the expanded reportable lists, with Department-published training materials, would spread the $7.4 million one-time familiarization and policy cost across an ordinary update cycle rather than imposing it at once. None of these alternatives appears in the RAF.

[27] 71 P.S. § 745.5(a)(12.1) (less stringent compliance or reporting requirements; less stringent schedules or deadlines; consolidation or simplification; performance standards; exemption). The Department states each was “not considered.” Department of Health, Regulatory Analysis Form, Question 27.

3. The Department Must Revise Its Regulatory Analysis and Repropose the Regulation

The deficiencies documented in Parts 1 and 2 are not matters of degree. The Department did not underestimate the cost of this regulation; it declined to estimate it entirely. Section 5(a) of the Regulatory Review Act specifies, in mandatory terms, what a regulatory analysis form "shall" contain, and the RAF the Department filed does not contain it.[28] The Act permits an agency to rely on the Office of the Budget's fiscal note for costs to the Commonwealth; it provides no such substitute for private-sector costs, which the agency must estimate itself. A statement that costs "will vary" is not an estimate. Costs that vary are estimated by ranges, averages or representative cases, as the Commenters have done in Appendix Tables 1 and 2; they are not recorded as "zero." The General Assembly enacted these requirements to "require the executive branch to justify its exercise of the authority to regulate before imposing hidden costs upon the economy of Pennsylvania" and because "[s]mall businesses bear a disproportionate share of regulatory costs and burdens."[29] A RAF that records $106 million in annual private and local government costs as $0 and every small-business accommodation as "not considered" is precisely the condition the Act was written to prevent.

The Commission Should Request a Revised RAF

The Commission's authority to correct this is time-limited by the Act itself, which is why the Commenters ask the Commission to act at the proposed stage. Under Section 5(g), the Commission may comment within thirty days after the close of public comment, its comments "shall specify the regulatory review criterion set forth in section 5.2 which the proposed regulation has not met," and "[i]f the commission does not comment on, make recommendations regarding or object to any portion of the proposed regulation within the time provided in this subsection, the commission shall be deemed to have approved that portion." The Commenters respectfully request that the Commission's comments identify

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[28] 71 P.S. § 745.5(a). The unmet requirements are: paragraph (4), "[e]stimates of the direct and indirect costs to the Commonwealth, to its political subdivisions and to the private sector," which the Department satisfies for the private sector with a figure of $0 reached by declining to estimate; paragraph (5), a statement of additional reporting, recordkeeping and paperwork "and an explanation of measures which have been taken to minimize these requirements," absent for a regulation composed principally of reporting mandates; paragraph (10), identification of financial impact on individuals and small businesses "and, when practicable, an evaluation of the benefits expected," which the Department had the prices and counts to perform and did not; paragraph (10.1), the small-business economic impact statement, each of whose four required elements is absent; paragraph (12), alternatives considered and rejected, satisfied only with stakeholder requests to make the rule stricter; paragraph (12.1), which directs that the agency "shall consider" each of five flexibility methods, all of which the Department states were "not considered"; and paragraph (14), a description of the data on which the regulation is based with "the burden of proving that the data is acceptable" on the agency, which the Department answers by stating it relied on none.

[29] 71 P.S. § 745.2(a), (c).

the following criteria under Section 5.2(b) as unmet, and direct the Department to submit a revised RAF before the regulation proceeds to final form:

- Section 5.2(b)(1)(i), (iii) and (iv): direct and indirect costs to the private sector, the estimated cost of required reports and paperwork, and the estimated cost of legal and consulting services, each of which the RAF records as zero or omits.
- Section 5.2(b)(1)(v) and (8): the impact of exempting or setting lesser standards for small businesses, and whether a less costly or less intrusive alternative was considered, neither of which the Department considered.
- Section 5.2(b)(3)(iii), (iv) and (v), and (7): need, reasonableness of requirements, and whether acceptable data is the basis of the regulation. A requirement whose cost the agency has declined to determine cannot be shown reasonable, and the Department explicitly states it relied on no data.
- Section 5.2(b)(6): compliance with the Act in promulgating the regulation, for the reasons stated above.

The revised RAF should contain actual estimates of direct and indirect private-sector costs by provision and by category of regulated party; an estimate of aggregate reporting and recordkeeping burden; the small-business economic impact statement Section 5(a)(10.1) requires; a regulatory flexibility analysis that considers each of the five methods in Section 5(a)(12.1); the alternatives the Department itself considered for each cost-imposing provision, including those in Part 2, and the reasons for their rejection; and the data on which each substantive change rests, with the showing of acceptability Section 5(a)(14) requires.

The Commission Should Request an Additional Comment Period

A revised analysis delivered for the first time at the final-form stage will not cure the defect, because the public will never see it in time to comment. The RAF is the document in which the agency states what the regulation will cost, whom it will affect and what alternatives it considered; it is the basis on which informed comment is possible. Commenters who relied on the Department's representation that the cost was zero, and who therefore did not undertake the analysis this letter presents, have had no opportunity to comment on the regulation's actual economic effect. At final form, that opportunity does not exist: the agency's response to comments and revised analysis go to the Commission and the committees, commenters who request it receive only the text of changes to the regulation, and public comment to the Commission closes forty-eight hours before its meeting.[30] PSEF

[30]71 P.S. §§ 745.5a(a), (b), (j). The Act's own remedy for a stale comment record is republication: an agency that fails to deliver a final-form regulation within two years of the close of comment "shall republish the regulation as a proposed regulation with a new public comment period." Id. § 745.5a(a). A regulation whose

therefore requests that the Commission recommend, in its Section 5(g) comments, that the Department issue an Advance Notice of Final Rulemaking publishing the revised RAF and any revisions to Annex A, with a comment period of not less than thirty days, before delivering the regulation in final form, as the Commission has recommended to this Department in prior rulemakings of comparable scope.[31]

The Rule as Proposed Lacks "Reasoned Basis"

Independently of the Commission's review, the regulation as proposed lacks the reasoned basis Pennsylvania law requires. An agency that has not determined what a regulation costs and has not compared it to alternatives has not made the determination the law requires it to make before regulating. Four separate sources of law establish that requirement.

- *The enabling statutes.* The Department invokes Section 16(a) of the Disease Prevention and Control Law, which authorizes the Advisory Health Board to regulate "any other matters it may deem advisable for the prevention and control of disease," and Section 2111(b) of The Administrative Code of 1929, which authorizes regulations "deemed by the Board to be necessary for the prevention of disease."[32] Both grants are conditioned on a judgment that the measure is "advisable" or "necessary." That judgment is a judgment that the rule's benefit warrants burden and that no lesser measure would serve; it cannot be made without knowing the burden and identifying the lesser measures. The RAF establishes that the Department knew neither. The Board approved this regulation on July 17, 2025, before the Department shared a final draft with sister agencies in December 2025. The Commenters ask the Department to state what economic analysis was before the Board when it made the determination of necessity on which its authority depends.
- *The Regulatory Review Act's declaration of purpose.* Section 2(a) states the General Assembly's purpose "to require the executive branch to justify its exercise of the authority to regulate before imposing hidden costs upon the economy of

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economic analysis is rewritten after the comment period closes presents the same problem in a different form.

[31]See Independent Regulatory Review Commission, Comments on Proposed Rulemaking, Department of Health Regulation Nos. 10-223 and 10-224 (Long-Term Care Nursing Facilities, Rulemakings 3 and 4) (2022), in which the Commission "suggested that the Department consider issuing an Advance Notice of Final Rulemaking to assist in reaching consensus," as recounted in the Department's final-form preamble, 52 Pa.B. (December 24, 2022), Pa.B. Doc. No. 22-2018. Pursuant to 71 P.S. § 745.5a(a)–(b), the Commenters request notice of the submission of the final-form regulation, a copy of all changes to the proposed regulation, and copies of the final-form Regulatory Analysis Form and the Department's response to comments at the time they are delivered to the Commission.

[32]35 P.S. § 521.16(a)(11); 71 P.S. § 541(b). Department of Health, Regulatory Analysis Form, Question 8.

Pennsylvania." Section 5(a) specifies the form that justification must take, and Section 5.2(b) the standards by which it is judged. These are the General Assembly's statement of what a lawfully promulgated regulation must be able to show. This regulation cannot show any of them because the Department did not perform the analysis that would permit it to.

- *The Commission's criteria*. Section 5.2(b)(3) directs that "clarity, feasibility and reasonableness" be determined by considering the "[n]eed for the regulation," the "[r]easonableness of requirements, implementation procedures and timetables for compliance by the public and private sectors," and "[w]hether acceptable data is the basis of the regulation."[33] These are the substantive attributes a regulation must possess to be in the public interest. A regulation whose requirements the agency has not costed, whose need the agency has not distinguished from existing voluntary reporting and existing standards of care, and which the agency states rests on no data, does not meet these standards.

- *The Administration's own regulatory principles*. The Governor's regulatory review order requires the agency head to attest that the regulation "addresses a compelling public need that can be best remedied by the promulgation of the regulation," and requires a written analysis containing "[a]n estimate of the costs or savings," "[a] cost/benefit analysis of the regulation," "[n]onregulatory alternatives considered and the reasons for their dismissal," and "[a]lternative regulatory schemes considered and the reasons for their dismissal."[34] The RAF contains no cost/benefit analysis, identifies no nonregulatory alternative, and records the cost as zero. The regulation was delivered to the Commission on June 4, 2026, which means the three offices the order designates certified that a $0-cost, no-alternatives analysis satisfied it. The Commenters ask the Department to identify the basis on which the Policy Office determined that no viable alternative exists to a regulation for which the Department identified none, and asks the Commission to request from the Office of the Budget the fiscal note prepared under Section 1.374(d) and the basis on which that office accepted a private-sector cost estimate of zero.

The Regulatory Review Act does not permit an agency to satisfy its analytical obligations by declaring them unsatisfiable. The Commenters ask the Commission to comment under

[33] 71 P.S. § 745.5b(b)(3)(iii)–(v). "Acceptable data" is defined as "[e]mpirical, replicable and testable data as evidenced in supporting documentation, statistics, reports, studies or research." Id. § 745.3.

[34] 4 Pa. Code § 1.374(a), (b)(12)–(15). Section 1.374(d) provides that the Governor's Policy Office "will review the request to determine that public interest is compelling, that no viable alternative to the regulation exists and that the costs of the regulation reasonably relate to the benefits," and that the Office of the Budget "will evaluate the cost analysis prepared by the agency and prepare a fiscal note." Section 1.374(e) provides that the agency "may not proceed" until the General Counsel, the Secretary of the Budget and the Policy Director have certified consistency with these principles.

Section 5(g), specifying the criteria in Section 5.2(b) identified above; to direct the Department to prepare a revised Regulatory Analysis Form that performs the analysis Section 5(a) requires; and to recommend that the Department publish that analysis for public comment through an Advance Notice of Final Rulemaking before the regulation proceeds. The Commenters ask the Department to do so without waiting to be directed.

Conclusion

In sum, we thank the Department for considering our comments on this proposed regulatory action. In light of the foregoing analysis, the question that must be asked is whether this rule, as proposed, meets the definition of "advisable" under the Disease Prevention and Control Law, and why such measures are now suddenly "necessary" more than 65 years after the underlying health statutes were first enacted without such measures. We urge the Department to reconsider the costliest elements of the proposed rule changes, or at the very least take the legally required steps to acknowledge their true cost in the final rule. However, rather than imposing such costly measures on citizens and businesses of the Commonwealth, we encourage the Department to instead consider measures that will *reduce* administrative costs and make care *more affordable* for Pennsylvanians.

As stated in the introduction, we do not question the sincere motives of the Department in attempting to improve public health and safety. However, whatever the merits of the authority sought, promulgating regulations without the justification required by the Regulatory Review Act is not a permissible means to that end. We ask the Department to give serious consideration to input from the regulated community and the public, including the undersigned, who are attempting to ensure that the Department can accomplish its mission with the benefit of as much information about costs, benefits, and unintended consequences as possible.

Sincerely,

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Dan Bartkowiak

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Appendix Table 1: Estimated Costs of Requirements the Department Scored at Zero or Omitted from Its Regulatory Analysis Form

PSEF estimates that the provisions the Department recorded as having "no overall fiscal impact," or did not address in its fiscal analysis, impose approximately $8,655,766 in recurring annual costs on the private regulated community, $8,361,519 on school districts and other political subdivisions, and $89,292,662 per year on parents, patients and their insurers, for a total of $106,309,947, plus approximately $11,851,810 in one-time implementation costs, offset by roughly $579,932 in annual savings. Superscript numbers refer to the notes following the table. [1]

New Requirement Description	Section Reference	Estimated Cost per Affected Party or Instance	Affected Parties (Instances)	Estimated Aggregate Cost
Recurring annual costs				
Report newly reportable conditions to PA-NEDSS (manual web entry) [2]	§ 27.21a	$32.09 per case report	1,173 new case reports per year entered manually [3]	$37,655
Report newly reportable respiratory and enteric virus results (manual labs) [4]	§ 27.22(b), (c)	$4.06 per result	40,649 newly reportable results per year entered manually [5]	$165,026
Obtain (laboratory) and supply (ordering provider) patient employer and pregnancy status on each reportable result [4]	§ 27.22(c)	$7.03 per result	94,269 reportable results per year (floor) [6]	$662,751
Report treatment provided for each tuberculosis and sexually transmitted disease case (second report per case) [7]	§ 27.33a	$16.05 per treatment report	74,450 reportable STD and TB cases per year [8]	$1,194,625
Manually enter each vaccine dose into PIERS [9]	§ 27.36	$2.97 per dose	770,000 doses per year entered manually [10]	$2,287,393
Abstract and report each birth defect case to the new registry [11]	§ 27.37	$36.22 per case	2,138 reportable birth defects per year [12]	$77,449
Maintain emergency department syndromic surveillance feed to mandatory 24-hour standard [13]	§ 27.4a	$3,498.31 per hospital system per year	75 hospital firms [14]	$262,373
Provide student access for Department contact tracing and partner services — school districts and charter schools [15]	§ 27.60c	$256.74 per visit	674 districts and charters (one visit per year) [16]	$173,040
Provide student access for Department contact tracing and partner services — colleges and universities [15]	§ 27.60c	$256.74 per visit	400 colleges and universities (one visit per year) [17]	$102,694
Exclude, track and readmit students under expanded exclusion chart — school nurse time [18]	§ 27.71a	$16.05 per added exclusion event	285,294 added student exclusion events per year [19]	$4,577,823
Parent misses work to care for excluded student (K–12; expanded exclusion chart and close-contact exclusion) [18]	§ 27.71a	$252.80 per lost work day	222,911 added exclusion-days of children under 13 requiring a parent to miss work [20]	$56,351,792
Hire substitutes for excluded instructional staff [18]	§ 27.71a	$151.20 per substitute-day	23,880 added instructional-staff exclusion-days requiring a substitute [21]	$3,610,656

New Requirement Description	Section Reference	Estimated Cost per Affected Party or Instance	Affected Parties (Instances)	Estimated Aggregate Cost
Screen temperatures and exclude children at lowered fever threshold — child care staff time [22]	§ 27.72	$5.38 per added exclusion event	50,344 added child exclusion events per year [23]	$270,761
Parent misses work to care for excluded child (child care; lowered fever threshold) [22]	§ 27.72	$252.80 per lost work day	65,447 added exclusion-days requiring a parent to miss work [24]	$16,544,977
Cover shifts for excluded child care staff [22]	§ 27.72	$106.05 per replacement shift	23,087 added staff exclusion-days requiring replacement [25]	$2,448,406
Add incremental prenatal hepatitis C test to standing prenatal orders and review result — nursing time [26]	§ 27.99a	$5.35 per incremental test	79,399 incremental tests per year [27]	$424,679
Incremental prenatal hepatitis C test (laboratory charge) [26]	§ 27.99a	$62.00 per test	79,399 incremental tests per year [27]	$4,922,738
Add incremental third-trimester HIV test to standing prenatal orders and review result — nursing time [28]	§ 27.99b	$5.35 per incremental test	134,978 incremental tests per year [29]	$721,954
Incremental third-trimester HIV test (laboratory charge) [28]	§ 27.99b	$85.00 per test	134,978 incremental tests per year [29]	$11,473,155
Subtotal — Recurring annual costs				**$106,309,947**
One-time implementation costs (first year)				
One-time policy and staff-training update for the expanded reportable list and new chart format [2]	§ 27.21a	$160.69 per facility	6,000 health care facilities [30]	$964,123
One-time practitioner familiarization with expanded reportable list [2]	§ 27.21a	$16.05 per practitioner	400,000 health care practitioners [31]	$6,418,400
Modify electronic case-reporting interface to add new conditions (one-time) [2]	§ 27.21a	$3,498.31 per hospital system	75 hospital firms [14]	$262,373
Update laboratory information system and electronic reporting feed for new conditions and data fields (one-time) [4]	§ 27.22(b), (c)	$1,784.66 per electronically reporting laboratory	250 laboratories reporting electronically [32]	$446,164
Build and test EHR-to-PIERS immunization reporting interface (one-time) [9]	§ 27.36	$1,784.66 per provider	1,425 non-reporting vaccine providers adopting an interface [33]	$2,543,135
Build reporting workflow to the new birth defects registry (one-time) [11]	§ 27.37	$1,784.66 per hospital	86 birthing hospitals [34]	$153,480
Legal review of student-consent and parental-notification procedures (one-time) [15]	§ 27.60c	$461.95 per district or charter	674 school districts and charter schools [35]	$311,357
Add standard § 27.60d partner-services notice to result letters, portal messages and result-delivery scripts (one-time template change) [36]	§ 27.60d	$44.62 per facility	6,000 health care facilities [37]	$267,698
Revise enrollment policies and immunization records for fixed immunization list (one-time) [38]	§ 27.77	$76.06 per child care setting	6,378 child care settings [39]	$485,080
Subtotal — One-time implementation costs (first year)				**$11,851,810**
Annual savings				

New Requirement Description	Section Reference	Estimated Cost per Affected Party or Instance	Affected Parties (Instances)	Estimated Aggregate Cost
Annual immunization status report eliminated (savings) [38]	§ 27.77	($38.03) per child care setting per year	6,378 child care settings [39]	($242,540)
Duplicate veterinary reports to the Department eliminated (savings) [40]	§§ 27.24a, 27.35	($52.72) per report avoided	6,400 duplicate reports avoided per year [41]	($337,392)
Subtotal — Annual savings				**($579,932)**
Net recurring annual cost (recurring costs less savings)				**$105,730,015**
Total first-year cost (recurring plus one-time, less savings)				**$117,581,825**
Department's estimate, regulated community, every year (Regulatory Analysis Form, Question 23)				*$0*

Notes to Appendix Table 1

1. Unless otherwise stated, cost per instance is hours per instance multiplied by the Pennsylvania mean hourly wage for the occupation shown in Appendix Table 2 (U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics, May 2025 State Estimates: Pennsylvania, mean hourly wage (Washington, DC: U.S. Department of Labor, 2026), https://www.bls.gov/oes/) and by a total-compensation multiplier of 1.42 for employer benefit costs (U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation—June 2025, USDL-25-1358 (Washington, DC: U.S. Department of Labor, September 12, 2025), https://www.bls.gov/news.release/ecec.nr0.htm). Hours per instance are PSEF assumptions stated in Appendix Table 2. Lost wages to parents are valued at the unloaded all-occupations mean wage. The Department's own figures are used for every count the Department provides; Census, BLS and federal statistical sources are used only where the Department provides none.

2. Proposed § 27.21a expands the list of diseases, infections and conditions that health care practitioners and facilities must report from 52 to 125. The Department concedes that practitioners and facilities that report manually "will need to allocate additional resources, including staff time," states that it "does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report," and records the cost as "no overall fiscal impact." Pennsylvania Department of Health, Regulatory Analysis Form: Communicable and Noncommunicable Diseases, 28 Pa. Code Chapter 27 (Proposed Rulemaking, IRRC No. 3490, June 4, 2026), Independent Regulatory Review Commission, https://irrc.state.pa.us/docs/3490/AGENCY/3490PRO.pdf, Questions 15 and 19.

3. Latent tuberculosis infections (newly practitioner-reportable) plus other newly reportable conditions. Active tuberculosis totaled 554 cases in 2021–2023, or 184.7 per year (Pennsylvania Department of Health, Bureau of Communicable Diseases, "Communicable Diseases, 2021–2023," EDDIE, https://www.pa.gov/agencies/health/health-statistics/health-statistics-a-to-z/notifiable-diseases---health-statistics-a-to-z (accessed September 2026)); PSEF assumes 10 latent infections reported per active case, yielding 1,847, plus an assumed 500 reports per year of the other newly listed conditions (about seven per added condition; the figure depends on the composition of the list and would be higher if any high-incidence condition is among the additions), for 2,347 new reports. Because the Department has no data on the share of reporters entering cases manually, PSEF assumes 50 percent; at 25 and 100 percent the row total is $18,828 and $75,310.

4. Proposed § 27.22 expands the laboratory reportable list from 63 to 116 and adds six data fields to every laboratory report (date of birth, gender, race, ethnicity, employer information, pregnancy status). The Department applies the same "insufficient data" formula and records no fiscal impact, while conceding the change "may require more work for the laboratories." Department of Health, Regulatory Analysis Form, Questions 15, 18 and 19.

5. 9,589 clinical laboratories, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15), multiplied by the small-firm share of Pennsylvania medical laboratories (117 of 138 firms under 500 employees; U.S. Census Bureau, Statistics of U.S. Businesses 2022: U.S. and States, 6-digit NAICS, Enterprise Employment Size (Washington, DC: U.S. Census Bureau, April 10, 2025), Pennsylvania), an assumed 10 newly reportable positive results per small laboratory per year for adenovirus, human metapneumovirus, parainfluenza, rhinovirus and norovirus, and a 50 percent manual-entry share. Most detections of these viruses come from multiplex PCR panels in laboratories that report electronically; this row is a floor.

6. Average annual STD and tuberculosis cases (74,450; Pennsylvania Department of Health, Bureau of Communicable Diseases, "Sexually Transmitted Diseases, 2021–2023," Enterprise Data Dissemination Informatics Exchange (EDDIE), https://www.pa.gov/agencies/health/health-statistics/health-statistics-a-to-z/sexually-transmitted-diseases---health-statistics-a-to-z (accessed September 2026)) plus the 15 non-STD conditions in the Department's published surveillance data (17,472; Department of Health, EDDIE, Communicable Diseases) plus newly reportable conditions (2,347). This is a floor: it counts only conditions for which the Department publishes case counts and omits, among others, Lyme disease, influenza, hepatitis and COVID-19 laboratory results, which alone would multiply it. The employer and pregnancy fields are not in current laboratory workflow and must be captured by the ordering provider and transmitted by the laboratory; the unit cost combines six minutes of laboratory staff time to request and enter the fields with six minutes of ordering-provider staff time to supply them. Applies to electronic and manual reporters alike.

7. Proposed § 27.33a requires a report of the treatment provided for tuberculosis and six sexually transmitted diseases, a second report on a case already reported at diagnosis. The Department concedes reporters "will need to allocate additional resources" and that the requirement "may result in additional costs up front," and records no fiscal impact. Department of Health, Regulatory Analysis Form, Questions 15, 18 and 19.

8. Average annual reportable STD and tuberculosis cases, 2021–2023: chlamydia 54,127; gonorrhea 18,842; primary and secondary syphilis 1,296; tuberculosis 185; total 74,450 (Department of Health, EDDIE, Sexually Transmitted Diseases; Department of Health, EDDIE, Communicable Diseases). Fifteen minutes per treatment report is a PSEF assumption. Treatment data are not transmitted in electronic laboratory reporting, so the requirement applies to all reporters.

9. Proposed § 27.36 requires every immunization administered outside Philadelphia to be reported to PIERS within 30 days unless the patient declines in writing. The Department states that 4,750 of approximately 21,000 vaccine providers do not currently report and "will need to establish a process for reporting, which may require additional staff or IT support," that it "does not currently have sufficient data to estimate the financial impact," and records no fiscal impact. Department of Health, Regulatory Analysis Form, Questions 15 and 19.

10. Statewide doses are a PSEF estimate from published coverage rates: 2.66 million Pennsylvania children under 18 (Department of Health, EDDIE, Communicable Diseases, population denominators) × about 2.3 doses per year (roughly 32 routine doses from birth through age 18 under the CDC child and adolescent schedule, plus annual influenza vaccination at 50.2 percent coverage), and 10.4 million adults × influenza (41.9 percent) and COVID-19 (about 23 percent) coverage, or about 12.9 million doses; other adult vaccines are omitted. Excluding Philadelphia's 11.9 percent of the population, which reports to its own registry, yields about 11.3 million, rounded to 11 million. Centers for Disease Control and Prevention, "Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025"; CDC, "Flu Vaccination Coverage, United States, 2024–25 Influenza Season," FluVaxView, https://www.cdc.gov/fluvaxview/coverage-by-season/2024-2025.html; CDC, COVIDVaxView, adult coverage dashboard, 2024–25 season; U.S. Census Bureau, Vintage 2024 Population Estimates: Pennsylvania (13.08 million) and United States (340.1 million). PSEF assumes 10 percent of doses are given by the 4,750 non-reporting providers (22.6 percent of providers, but disproportionately small) and that 70 percent of those 1,100,000 doses are entered manually at six minutes each. The Department administers PIERS and holds the actual dose and provider counts.

11. Proposed § 27.37 creates a birth defects registry and mandatory reporting of congenital anomalies. The Department estimates its own costs at roughly $1.5 million per year but states the regulated community "will need to establish a system for reporting" and that it "does not have sufficient data" to estimate that cost. Department of Health, Regulatory Analysis Form, Questions 15, 19 and 21.

12. The Department's birth certificate data record 418 births per year with one of eleven major anomalies (2,088 over 2020–2024; Pennsylvania Department of Health, "Birth Defects, 2020–2024," Pennsylvania Birth Certificate Dataset, EDDIE, https://www.pa.gov/agencies/health/health-statistics/health-statistics-a-to-z/birth-defects---health-statistics-a-to-z (accessed September 2026)). CDC estimates that about 1 in 33 births has a major birth defect (Centers for Disease Control and Prevention, "Data and Statistics on Birth Defects," National Center on Birth Defects and Developmental Disabilities, https://www.cdc.gov/birth-defects/data-research/ (accessed September 2026)), which applied to 127,330 Pennsylvania births in 2024 (Pennsylvania Department of Health, Bureau of Health Statistics and Registries, Pennsylvania Vital Statistics 2024: Reported Pregnancies, Table E-1 (Harrisburg: Department of Health, 2026), https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/healthstatistics/vitalstatistics/pavitalstatistics/documents/pa_vital_statistics_pregnancy_2024.pdf) yields 3,858. The table uses the midpoint, 2,138; at the Department's own figure the row is $15,127 and at the CDC prevalence $139,771. One hour per case is a PSEF assumption.

13. Proposed § 27.4a makes hospital emergency department visit reporting mandatory within 24 hours and authorizes the Department to require "other data elements deemed necessary by the Department." The provision does not appear in the Department's fiscal analysis; the preamble asserts "no impact on hospitals" because reporting is currently voluntary.

14. Pennsylvania general medical and surgical hospital firms (NAICS 622110), all sizes (Census Bureau, Statistics of U.S. Businesses 2022); the Department gives no hospital count, and many firms operate multiple hospitals and emergency departments. Pennsylvania hospitals already transmit emergency department data to the National Syndromic Surveillance Program voluntarily; the increment is compliance with a mandatory 24-hour standard and response to Department data-element changes, which the open-ended clause in § 27.4a leaves unbounded. Forty hours of internal information-technology time per firm per year for that incremental work is a PSEF assumption and excludes vendor fees.

15. Proposed § 27.60c requires schools, colleges and universities to provide "reasonable and timely access" to students, including during instructional time, for contact tracing and partner services. The Department concedes the provision "may result in a time disruption to schools" and records no fiscal impact "because of the inability to estimate a specific cost." Department of Health, Regulatory Analysis Form, Question 19.

16. 500 school districts and 174 charter and cyber charter schools, the Department's figures (Department of Health, Regulatory Analysis Form, Question 15). PSEF assumes one contact-tracing or partner-services visit per entity per year; the Department and local health departments hold the actual counts. Four hours of school staff time per visit is a PSEF assumption.

17. Approximately 400 colleges and universities, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15), at the same assumed one visit per year and four staff hours per visit. Colleges and universities include private institutions, state-related and state-owned universities, and county-sponsored community colleges; they are grouped separately from school districts and charter schools.

18. Proposed § 27.71a expands the exclusion and readmission chart by 18 conditions, extends exclusion to close contacts, and applies the chart to schools, colleges and universities, child care settings, food handlers and health care practitioners. The Department concedes schools and child care settings "may also be financially impacted by an increase in staff and student absences," possibly "necessitating the need for substitute teachers," and that individuals will bear "a financial impact due to individuals missing time from work or school," and records no fiscal impact for either. Department of Health, Regulatory Analysis Form, Question 19. Exclusion of food handlers and health care practitioners is not costed because existing law already requires exclusion of symptomatic food employees (Pennsylvania Food Code, 7 Pa. Code Chapter 46, adopting FDA Food Code § 2-201.12) and existing infection-control practice already excludes symptomatic health care workers.

19. Baseline illness absence: Pennsylvania children ages 5–17 (1,984,307, from the Department's EDDIE population denominators; Department of Health, EDDIE, Communicable Diseases) multiplied by about 2.9 school days missed per child per year for illness or injury, computed from the National Health Interview Survey distribution (28.5 percent missing 1–2 days, 25.9 percent 3–5, 9.4 percent 6–10, 4.4 percent 11 or more; Lindsey I. Black and Vicki Benson, Tables of Summary Health Statistics for U.S. Children: 2017 National Health Interview Survey, Table C-6a (Hyattsville, MD: National Center for Health Statistics, 2018), https://ftp.cdc.gov/pub/health_Statistics/nchs/NHIS/SHS/2017_SHS_Table_C-6.pdf) using bin midpoints 1.5, 4, 8 and 15, for 5,705,874 baseline days. National rates are applied to Pennsylvania's population because the Commonwealth publishes no illness-absence data. PSEF assumes the added conditions and close-contact exclusion increase exclusion-days by 10 percent (570,587 days); at 5 and 20 percent the three § 27.71a rows total $32,270,136 and $129,080,542. Staff time is counted per exclusion event, not per day; PSEF assumes an average exclusion of two days, so 570,587 added days are 285,294 events, at 15 minutes of school nurse time each. The effect of the § 27.72 fever threshold on school-age children is not separately counted; the estimate is conservative in that respect.

20. Added exclusion-days (note 19) multiplied by 60.1 percent (1,192,625 of 1,984,307), the share of Pennsylvania children ages 5–17 who are under 13 and therefore assumed to require a parent at home when excluded (children 13 and older are assumed able to stay home alone; derived from the Department's EDDIE population denominators, Department of Health, EDDIE, Communicable Diseases, taking ages 5–12 as eight-tenths of the 5–14 group), and by 65 percent, the approximate share of Pennsylvania children whose resident parents are all in the labor force (U.S. Census Bureau, American Community Survey 2023 1-Year Estimates, Table B23008, Pennsylvania). Each such day costs one parent a full eight-hour day at the Pennsylvania all-occupations mean hourly wage of $31.60 (BLS, OEWS May 2025, Pennsylvania); the mean rather than the median is used because the estimate is an aggregate across all affected households. Benefits are not added because the loss is measured from the individual's perspective.

21. 199,000 school employees, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15), of whom approximately 60 percent are classroom teachers and other instructional staff for whom a substitute is engaged when absent (Pennsylvania Department of Education, Professional Personnel Summary, 2023–24, approximately 122,000 classroom teachers); non-instructional staff absences are not costed. Baseline of 2.5 illness absence days per employee per year is the Bureau of Labor Statistics lost-worktime rate for illness or injury of about 1.3 percent of usual hours among full-time workers (U.S. Bureau of Labor Statistics, Current Population Survey, Annual Averages, Table 47, "Absences from Work of Employed Full-Time Wage and Salary Workers by Occupation and Industry," https://www.bls.gov/cps/cpsaat47.htm) applied to a 190-day school year. The 10 percent increase is the same estimating assumption applied to students under § 27.71a; 80 percent of added days are assumed to require a paid substitute: 23,880 substitute-days of seven hours. Substitutes are valued at the unloaded wage because per-diem substitutes typically receive no employer benefits.

22. Proposed § 27.72 lowers the exclusion fever threshold from 102°F (oral or axillary) to 100.4°F (rectal, ear, forehead), 100°F (oral) or 99°F (axillary) and revises the symptom list. Symptom-based exclusion already applies to child care group settings under existing § 27.76(a) and under Department of Human Services regulations at 55 Pa. Code § 3270.137, which the Department acknowledges (Regulatory Analysis Form, Question 13); the threshold and list changes are the new elements. The Department concedes the change will result in "more frequent exclusion of children from those settings" (Department of Health, Regulatory Analysis Form, Question 13) but does not cost it.

23. Licensed child care capacity of 411,949 (Pennsylvania Department of Human Services, Office of Child Development and Early Learning, "Child Care Certification and Keystone STARS Rating Details," dashboard, State Fiscal Year 2026–2027 (July), refreshed August 19, 2026) multiplied by an assumed 85 percent utilization, or 350,157 children, multiplied by the same 2.9 illness-absence days per child (conservative for children under five), for 1,006,875 baseline days. Because child care settings already exclude on the § 27.72 symptom list under existing § 27.76 and 55 Pa. Code § 3270.137, only the lowered fever threshold and the revised list are new; PSEF assumes they increase exclusion-days by 10 percent (100,688 days), the same rate assumed for schools. At 5 and 20 percent the three § 27.72 rows total $9,632,072 and $38,528,288. Staff time is counted per exclusion event at an assumed average of two days per exclusion, or 50,344 events, at 15 minutes each. Licensed capacity includes school-age before- and after-care slots, and some centers already exclude at 100.4°F under their own policies; both cut toward a smaller increment. The effect of the § 27.71a expanded chart on child care children is not separately counted.

24. Added child care exclusion-days (note 23) multiplied by the 65 percent parental labor-force share and one eight-hour day at the all-occupations mean wage, as in the K–12 calculation. All children in child care are assumed to require a parent at home.

25. 96,197 child care employees, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15), multiplied by a three-day illness-absence baseline (the BLS lost-worktime rate of about 1.3 percent of usual hours, Current Population Survey Table 47, applied to a 250-day year for year-round child care staff), the same 10 percent increase assumed for children under § 27.72, and an 80 percent replacement share: 23,087 replacement shifts of seven hours at the unloaded childcare worker wage.

26. Proposed § 27.99a requires a hepatitis C blood test for every pregnant patient unless the patient objects. The Department cites a Quest Diagnostics list price of $62 and patient co-payments of $25 to $30 and concludes it is "estimating no fiscal cost." Department of Health, Regulatory Analysis Form, Question 19. Because CDC has recommended universal hepatitis C screening in each pregnancy since 2020 (Sarah Schillie et al., "CDC Recommendations for Hepatitis C Screening Among Adults—United States, 2020," MMWR Recommendations and Reports 69, no. 2 (April 10, 2020): 1–17), only tests not already performed are counted; PSEF assumes 50 percent of pregnancies are currently screened.

27. 158,798 reported pregnancies to Pennsylvania residents in 2024 (Department of Health, Pennsylvania Vital Statistics 2024: Reported Pregnancies) multiplied by the 50 percent not currently screened: 79,399 incremental tests. Five minutes of registered nurse time per added test, to add the test to the standing prenatal order set and review the result, is a PSEF assumption; physician counseling time is not counted because the test is drawn with the existing prenatal panel. Counting all pregnancies, the two § 27.99a rows total $10,694,834.

28. Proposed § 27.99b requires HIV blood tests in the first and third trimester of every pregnancy unless the patient objects. The Department cites Quest list prices of $85 and $282 and concludes it is "estimating no fiscal cost." Department of Health,

Regulatory Analysis Form, Question 19. First-trimester screening has been standard of care since 2006 and is treated as zero incremental cost; CDC recommends repeat third-trimester testing only in high-prevalence jurisdictions or for high-risk patients (Bernard M. Branson et al., "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings," MMWR Recommendations and Reports 55, no. RR-14 (September 22, 2006): 1–17), so the universal third-trimester test is treated as 85 percent incremental.

29. 158,798 pregnancies multiplied by the 85 percent not currently receiving a third-trimester repeat test: 134,978 incremental tests. Nursing time as in note 27. Counting both tests for all pregnancies, the two § 27.99b rows total $28,694,375.

30. 6,000 health care facilities, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15). Two hours of manager time per facility is a PSEF assumption.

31. 400,000 health care practitioners, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15). Fifteen minutes per practitioner to review the expanded list and new reporting chart is a PSEF assumption; the registered nurse wage is used as a conservative proxy for a group that includes physicians, dentists, nurse practitioners and other licensed practitioners.

32. PSEF assumes 250 Pennsylvania laboratories report electronically; the Department's Bureau of Laboratories maintains the actual participation list. Forty hours per laboratory is a PSEF assumption and excludes vendor fees.

33. 4,750 vaccine providers not currently reporting to PIERS, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15). PSEF assumes 30 percent will build an electronic interface and 70 percent will enter doses manually. Forty hours per interface is a PSEF assumption and excludes EHR vendor interface fees.

34. 86 hospitals with reporting capability in the Department's neonatal abstinence syndrome surveillance system in 2022, used as a proxy for birthing hospitals (Pennsylvania Department of Health, Bureau of Family Health and Bureau of Epidemiology, Neonatal Abstinence Syndrome: 2022 Report (Harrisburg: Department of Health, September 2024), 23, describing "86 active hospitals with iCMS reporting capabilities" after closures of labor and delivery units in three counties). Further closures since 2022 would reduce the count. Forty hours per hospital is a PSEF assumption.

35. 500 school districts and 174 charter and cyber charter schools (Department of Health, Regulatory Analysis Form, Question 15). Four hours of solicitor time per entity to review parental-notification and minor-consent procedures under 35 P.S. § 10103 is a PSEF assumption.

36. Proposed § 27.60d requires any person providing STD or HIV test results to inform the patient that the Department may contact them for partner services. Not addressed in the Department's fiscal analysis.

37. Proposed § 27.60d attaches to any person "providing sexually transmitted disease, HIV or related test results to a patient" and is not limited to positive results or reported cases; it does not, however, prescribe the form of the notice. PSEF therefore costs it as a one-time change to result letters, patient-portal message templates and result-delivery scripts at each of the Department's 6,000 health care facilities (Department of Health, Regulatory Analysis Form, Question 15), at one hour of health information staff time per facility; physician practices that are not facilities are omitted, so the figure is a floor. If the Department reads the provision to require an individual verbal notice with each result, the cost becomes recurring: dividing average annual reported STD and tuberculosis cases (74,450; Department of Health, EDDIE, Sexually Transmitted Diseases) by an assumed average test positivity of 5 percent yields approximately 1,489,000 results delivered per year, which at one minute each at the loaded registered nurse rate ($64.18 per hour) is about $1,592,833 per year; limited to positive results it would be about $79,642. The Department's laboratory reporting system receives every result and holds the actual count.

38. Proposed § 27.77 fixes the child care immunization list in regulation, accepts natural-immunity documentation, adds a moral or ethical exemption, and replaces the annual immunization status report with a report on request. The Department states settings "may be required to update policies" and that eliminating the annual report "will reduce the administrative burden," without figures. Department of Health, Regulatory Analysis Form, Question 13.

39. 6,378 child care settings, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15); the OCDEL dashboard reports 6,538 licensed facilities as of July 2026 (OCDEL, Child Care Certification dashboard). Two director hours per setting for the one-time policy revision, and one director hour per setting per year saved by eliminating the annual report, are PSEF assumptions.

40. Proposed §§ 27.24a and 27.35 limit veterinarian reporting to zoonotic diseases not already reported to the Department of Agriculture. The Department states this "may result in a cost savings through efficiencies" but is "estimating no fiscal savings." Department of Health, Regulatory Analysis Form, Question 19.

41. 3,200 veterinarians, the Department's figure (Department of Health, Regulatory Analysis Form, Question 15), multiplied by an assumed two duplicate reports per veterinarian per year avoided, at 30 minutes each.

Scope. Appendix Table 1 includes only provisions for which the Department either conceded a cost and recorded it as zero, or omitted from its fiscal analysis. It excludes provisions whose cost is contingent on future Department action (§§ 27.60, 27.60b and 27.191, which expand disease-control, entry and animal-restriction authority); provisions with de minimis or no incremental cost (§§ 27.22a, 27.32d–e, 27.162 and 27.203–204; § 27.31, which the Department states is proposed "to align with current practice" because brain-related tumors are already reported to the Pennsylvania Cancer Registry (Preamble, discussion of § 27.31); § 27.33b, because animal bites are already reportable under existing § 27.21a; and § 27.30, because the Department's own surveillance report states that "[e]ffective January 1, 2020, all hospitals in Pennsylvania are required to report NAS cases" and that 78 of the 86 hospitals with reporting capability in its surveillance system reported through the Department's iCMS system in 2022, so mandatory reporting adds no incremental abstraction cost (Neonatal Abstinence Syndrome: 2022 Report, 6, 23)); and activities that generate revenue rather than cost to the performing party (laboratory performance of the prenatal tests, whose cost appears in the test-charge rows). Costs are incremental to current practice throughout.

Appendix Table 2: Derivation of Cost per Affected Party or Instance

Appendix Table 2 shows the hours, wage basis and loaded rate behind each cost-per-party figure in Appendix Table 1, grouped by the party that bears the cost. Multiplying the last column by the corresponding count in Appendix Table 1 approximately reproduces the aggregate cost; aggregates are computed from unrounded counts.

Requirement	Section	Hours per Instance	Wage or Unit Price Basis	Loaded Rate	Cost per Party or Instance
Physician practices, clinics, hospitals					
Report newly reportable conditions to PA-NEDSS (manual web entry)	§ 27.21a	0.5 [2]	Registered Nurses (29-1141), $45.20/hr [1]	$64.18/hr	**$32.09**
Report treatment provided for each tuberculosis and sexually transmitted disease case (second report per case)	§ 27.33a	0.25 [2]	Registered Nurses (29-1141), $45.20/hr [1]	$64.18/hr	**$16.05**
Health care facilities					
One-time policy and staff-training update for the expanded reportable list and new chart format (one-time)	§ 27.21a	2 [2]	Medical and Health Services Managers (11-9111), $56.58/hr [1]	$80.34/hr	**$160.69**
Add standard § 27.60d partner-services notice to result letters, portal messages and result-delivery scripts (one-time template change)	§ 27.60d	1 [2]	Health Information Technologists and Medical Registrars (29-9021), $31.42/hr [1]	$44.62/hr	**$44.62**
Health care practitioners					
One-time practitioner familiarization with expanded reportable list (one-time)	§ 27.21a	0.25 [2]	Registered Nurses (29-1141), conservative proxy for mixed practitioner types, $45.20/hr [1,3]	$64.18/hr	**$16.05**
Hospitals					
Modify electronic case-reporting interface to add new conditions (one-time)	§ 27.21a	40 [2]	Software Developers (15-1252), $61.59/hr [1]	$87.46/hr	**$3,498.31**
Maintain emergency department syndromic surveillance feed to mandatory 24-hour standard	§ 27.4a	40 [2]	Software Developers (15-1252), $61.59/hr [1]	$87.46/hr	**$3,498.31**
Clinical and physician-office laboratories					
Report newly reportable respiratory and enteric virus results (manual labs)	§ 27.22(b), (c)	0.1 [2]	Clinical Laboratory Technologists and Technicians (29-2010), $28.59/hr [1]	$40.60/hr	**$4.06**
Clinical laboratories and ordering providers					
Obtain (laboratory) and supply (ordering provider) patient employer and pregnancy status on each reportable result	§ 27.22(c)	0.1 [2]	Clinical Laboratory Technologists (29-2010), $28.59, plus Medical Assistants (31-9092), $20.92, combined, $49.51/hr [1]	$70.30/hr	**$7.03**
Clinical laboratories (electronic reporters)					
Update laboratory information system and electronic reporting feed for new conditions and data fields (one-time)	§ 27.22(b), (c)	40 [2]	Health Information Technologists and Medical Registrars (29-9021), $31.42/hr [1]	$44.62/hr	**$1,784.66**
Vaccine providers not currently reporting (practices, pharmacies, nursing homes)					

Requirement	Section	Hours per Instance	Wage or Unit Price Basis	Loaded Rate	Cost per Party or Instance
Build and test EHR-to-PIERS immunization reporting interface (one-time)	§ 27.36	40 [2]	Health Information Technologists and Medical Registrars (29-9021), $31.42/hr [1]	$44.62/hr	**$1,784.66**
Manually enter each vaccine dose into PIERS	§ 27.36	0.1 [2]	Medical Assistants (31-9092), $20.92/hr [1]	$29.71/hr	**$2.97**
Birthing hospitals, NICUs, pediatric and genetics practices					
Abstract and report each birth defect case to the new registry	§ 27.37	1 [2]	Medical Records Specialists (29-2072), $25.51/hr [1]	$36.22/hr	**$36.22**
Birthing hospitals					
Build reporting workflow to the new birth defects registry (one-time)	§ 27.37	40 [2]	Health Information Technologists and Medical Registrars (29-9021), $31.42/hr [1]	$44.62/hr	**$1,784.66**
School districts and charter schools (local government)					
Provide student access for Department contact tracing and partner services — school districts and charter schools	§ 27.60c	4 [2]	Registered Nurses (29-1141), school nurses, $45.20/hr [1]	$64.18/hr	**$256.74**
Legal review of student-consent and parental-notification procedures (one-time)	§ 27.60c	4 [2]	Lawyers (23-1011), $81.33/hr [1]	$115.49/hr	**$461.95**
Exclude, track and readmit students under expanded exclusion chart — school nurse time	§ 27.71a	0.25 [2]	Registered Nurses (29-1141), school nurses, $45.20/hr [1]	$64.18/hr	**$16.05**
Hire substitutes for excluded instructional staff	§ 27.71a	7 [2]	Substitute Teachers, Short-Term (25-3031), unloaded, $21.60/hr [1]	$21.60/hr	**$151.20**
Colleges and universities					
Provide student access for Department contact tracing and partner services — colleges and universities	§ 27.60c	4 [2]	Registered Nurses (29-1141), campus health staff, $45.20/hr [1]	$64.18/hr	**$256.74**
Parents of K–12 students					
Parent misses work to care for excluded student (K–12; expanded exclusion chart and close-contact exclusion)	§ 27.71a	8 [2]	All Occupations (00-0000), unloaded, $31.60/hr [1]	$31.60/hr	**$252.80**
Child care providers					
Screen temperatures and exclude children at lowered fever threshold — child care staff time	§ 27.72	0.25 [2]	Childcare Workers (39-9011), $15.15/hr [1]	$21.51/hr	**$5.38**
Cover shifts for excluded child care staff	§ 27.72	7 [2]	Childcare Workers (39-9011), unloaded, $15.15/hr [1]	$15.15/hr	**$106.05**
Revise enrollment policies and immunization records for fixed immunization list (one-time)	§ 27.77	2 [2]	Education and Childcare Administrators (11-9031), $26.78/hr [1]	$38.03/hr	**$76.06**
Annual immunization status report eliminated (savings)	§ 27.77	1 [2]	Education and Childcare Administrators (11-9031), $26.78/hr [1]	$38.03/hr	**($38.03)**
Parents of children in child care					

Requirement	Section	Hours per Instance	Wage or Unit Price Basis	Loaded Rate	Cost per Party or Instance
Parent misses work to care for excluded child (child care; lowered fever threshold)	§ 27.72	8 [2]	All Occupations (00-0000), unloaded, $31.60/hr [1]	$31.60/hr	**$252.80**
Obstetric, family medicine and midwifery practices					
Add incremental prenatal hepatitis C test to standing prenatal orders and review result — nursing time	§ 27.99a	0.083 [2]	Registered Nurses (29-1141), $45.20/hr [1]	$64.18/hr	**$5.35**
Add incremental third-trimester HIV test to standing prenatal orders and review result — nursing time	§ 27.99b	0.083 [2]	Registered Nurses (29-1141), $45.20/hr [1]	$64.18/hr	**$5.35**
Pregnant patients and their insurers					
Incremental prenatal hepatitis C test (laboratory charge)	§ 27.99a	— [2]	Quest Diagnostics list price cited by Department, $62.00 per test [1]	—	**$62.00**
Incremental third-trimester HIV test (laboratory charge)	§ 27.99b	— [2]	Quest Diagnostics list price cited by Department, $85.00 per test [1]	—	**$85.00**
Veterinary practices					
Duplicate veterinary reports to the Department eliminated (savings)	§§ 27.24a, 27.35	0.5 [2]	Veterinarians (29-1131), $74.25/hr [1]	$105.43/hr	**($52.72)**

Notes to Appendix Table 2

1. Wages are May 2025 Pennsylvania mean hourly wages by Standard Occupational Classification code (BLS, OEWS May 2025, Pennsylvania). Loaded rate = wage × 1.42 (BLS, Employer Costs for Employee Compensation). Parents' lost wages, substitute teachers and replacement child care staff are unloaded; per-diem substitutes and replacement staff typically receive no employer benefits. Where the basis is a unit price rather than a wage, the price is the Quest Diagnostics list price cited by the Department (Department of Health, Regulatory Analysis Form, Question 19).

2. Hours per instance are PSEF assumptions: 30 minutes for a new PA-NEDSS case report; 15 minutes for a treatment report on a case already in the system; one hour for a registry case abstraction; six minutes for a manual vaccine dose entry or laboratory data-field completion; five minutes of nurse time per added prenatal test; four hours of school staff time per contact-tracing visit; 15 minutes of nurse or child care staff time per exclusion event (an exclusion is assumed to average two days); 15 minutes per practitioner and two hours per facility for one-time familiarization and policy updates; one hour per facility for the one-time § 27.60d notice template change; 40 hours of internal information-technology time per one-time interface change (vendor fees excluded); seven hours per substitute or replacement shift; eight hours per parent lost work day.

3. The registered nurse wage is used as a conservative proxy for the mixed practitioner group (physicians, dentists, nurse practitioners and other licensed practitioners) in § 27.21a.

Appendix Table 3: Department Figures with Which PSEF Disagrees

Appendix Table 3 lists the estimates and statements in the Department's Regulatory Analysis Form that PSEF's independent analysis contradicts, the independent figure, and its basis. Where the Department supplied a count that PSEF does not dispute (practitioners, facilities, laboratories, vaccine providers, school and child care entities, veterinarians), PSEF used the Department's figure and it does not appear here.

Estimate	Department Figure	PSEF Independent Estimate	Basis for Independent Estimate
Annual cost to the regulated community, political subdivisions and the public of all provisions	$0 in every year FY2025-26 through FY2030-31 (Question 23); $0 to local government	$105,730,015 recurring, net of savings; $11,851,810 one-time	Sum of Appendix Table 1. Every volume figure is from the Department's own Regulatory Analysis Form, its EDDIE and vital statistics publications, the OCDEL dashboard, or free Census and BLS products released before June 4, 2026, except PSEF assumptions stated in the notes to Appendix Table 1.
Number of small businesses affected — offices of physicians	"Does not have sufficient data to determine the number" (Questions 15, 24)	3,089 of 3,180 firms under 500 employees; approximately 3,066 under the $16 million SBA receipts standard	Census Bureau, Statistics of U.S. Businesses 2022, NAICS 621111; receipts share from U.S. Census Bureau, Statistics of U.S. Businesses 2022: U.S., 6-digit NAICS, Enterprise Receipts Size, applied to the Pennsylvania firm count. SUSB counts enterprises, not practice locations; Pennsylvania's 2.4 percent share of U.S. physician-office firms is below its 3.9 percent population share because many Pennsylvania practices are owned by health systems and counted under the parent enterprise.
Number of small businesses affected — dental and other practitioner offices	"Does not have sufficient data" (Questions 15, 24)	Dentists 4,155 of 4,172; other practitioners 541 of 550 under 500 employees	Census Bureau, Statistics of U.S. Businesses 2022, NAICS 621210, 621399.
Number of small businesses affected — clinical laboratories	"Does not have sufficient data" (Questions 15, 24)	117 of 138 medical laboratory firms under 500 employees; approximately 128 under the $41.5 million SBA standard	Census Bureau, Statistics of U.S. Businesses 2022, NAICS 621511. The Department's 9,589 laboratories include physician-office and hospital laboratories not classified in NAICS 621511.
Number of small businesses affected — home health agencies	"Does not have sufficient data" (Questions 15, 24)	860 of 937 firms under 500 employees	Census Bureau, Statistics of U.S. Businesses 2022, NAICS 621610.
Number of small businesses affected — child care group settings	"Does not have sufficient data" (Questions 15, 24)	2,859 of 2,885 firms under 500 employees; 6,538 licensed facilities	Census Bureau, Statistics of U.S. Businesses 2022, NAICS 624410; OCDEL, Child Care Certification dashboard.
Number of small businesses affected — veterinary offices	"Does not have sufficient data" (Questions 15, 24)	992 of 1,010 firms under 500 employees	Census Bureau, Statistics of U.S. Businesses 2022, NAICS 541940.
Number of small businesses affected — pharmacies	Not addressed	787 of 805 firms under 500 employees	Census Bureau, Statistics of U.S. Businesses 2022, NAICS 446110 (456110 in NAICS 2022).
Cost to pregnant patients of mandatory prenatal HCV and HIV testing (§§ 27.99a, 27.99b)	"Estimating no fiscal cost" despite citing test prices of $62, $85 and $282 (Question 19)	$16,395,893 per year in incremental test charges ($36,841,136 gross)	Department's own Quest list prices multiplied by 158,798 reported pregnancies (Department of Health, Pennsylvania Vital Statistics 2024: Reported Pregnancies), incremental to current screening uptake (Appendix Table 1 notes).
Neonatal abstinence syndrome reporting (§ 27.30)	Pennsylvania "relies on voluntary reporting" (Question 12)	Reporting has been mandatory since January 1, 2020; 78 of the 86 hospitals with reporting	Pennsylvania Department of Health, Bureau of Family Health and Bureau of Epidemiology, Neonatal Abstinence Syndrome: 2022 Report (Harrisburg:

Estimate	Department Figure	PSEF Independent Estimate	Basis for Independent Estimate
		capability reported 1,254 cases for 2022 through the Department's iCMS system	Department of Health, September 2024), 4, 6, 23 (the fifth annual report in the series).
Provider-side cost of birth defects registry reporting (§ 27.37)	"Does not have sufficient data" (Question 19)	$77,449 per year; $153,480 one-time	The Department's own EDDIE birth-certificate data record 418 anomalies per year (Department of Health, EDDIE, Birth Defects); CDC prevalence yields 3,858 (CDC, Data and Statistics on Birth Defects).
Impact of mandatory emergency department reporting on hospitals (§ 27.4a)	"No impact on hospitals" (preamble); not in fiscal analysis	$262,373 per year, excluding open-ended "other data elements"	75 hospital firms (Census Bureau, Statistics of U.S. Businesses 2022) × 40 IT hours × software developer wage. The Department's own Question 12 concedes current reporting is voluntary.
Cost to schools of contact-tracing access (§ 27.60c)	"Inability to estimate a specific cost"; $0 (Question 19)	$275,734 per year; $311,357 one-time	Department's own school entity counts (Question 15) × one visit per year × four staff hours; solicitor review four hours per district and charter.
Cost of expanded exclusion chart and fever threshold to schools, child care and parents (§§ 27.71a, 27.72)	"Not able to estimate a specific cost"; $0 (Questions 13, 19)	$83,804,415 per year (range $41,902,208 to $167,608,830)	Department's own EDDIE population and staff counts; NHIS illness-absence distribution (Black and Benson, Summary Health Statistics 2017, Table C-6a); OCDEL capacity; PSEF uplift assumptions stated in Appendix Table 1 notes.
Savings to veterinarians from eliminating duplicate reporting (§§ 27.24a, 27.35)	"May result in a cost savings"; "estimating no fiscal savings" (Question 19)	$337,392 per year	Department's 3,200 veterinarians × two reports × 30 minutes × veterinarian wage (BLS, OEWS May 2025, Pennsylvania).
Data relied upon for the regulation	"The Department did not rely on data as the basis for this regulation" (Question 28)	Department publishes the case counts, birth data, population denominators and provider counts used throughout Table 1	Department of Health, EDDIE, Sexually Transmitted Diseases; Department of Health, EDDIE, Communicable Diseases; Department of Health, EDDIE, Birth Defects; Department of Health, Pennsylvania Vital Statistics 2024: Reported Pregnancies. Section 5(a)(14) of the Regulatory Review Act, 71 P.S. § 745.5(a)(14), places on the agency the burden of describing the data on which the regulation is based.
Regulatory flexibility methods for small businesses	Each of five statutory methods "not considered" (Question 27)	Not applicable — Section 5(a)(12.1) of the Act directs that the agency "shall consider" each method	71 P.S. § 745.5(a)(12.1).

Notes to Appendix Table 3

1. Small-business counts use the Census Bureau's enterprise employment-size classes because the Bureau does not publish receipts-size data by state. Applying the national distribution of firms by receipts within each industry to the Pennsylvania firm count yields figures within one to three percent of the under-500-employee counts for every health services industry shown, so the two methods are interchangeable for this purpose. The Small Business Administration thresholds referenced are those in 13 C.F.R. § 121.201 effective March 17, 2023.

2. The Statistics of U.S. Businesses release used here was published April 10, 2025, fourteen months before the Department delivered the Regulatory Analysis Form to the Commission on June 4, 2026.