COMMONWEALTH OF PENNSYLVANIA

TOM WOLF
GOVERNOR

JOSH SHAPIRO
ATTORNEY GENERAL

July 31, 2018

Via Federal eRulemaking Portal

The Honorable Alex M. Azar II
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Comments on Proposed Rule, *Compliance With Statutory Program Integrity Requirements*, Docket No. HHS-OS-2018-0008, 83 Fed. Reg. 25,502

Dear Secretary Azar:

We submit these comments on the proposed rule issued by the United States Department of Health and Human Services ("HHS") entitled "Compliance with Statutory Program Integrity Requirements" ("Proposed Rule").[1]

If adopted, the Proposed Rule would deny women, men, and families across the Commonwealth of Pennsylvania and the nation access to comprehensive, evidence-based, nondirective family planning services. It would place the federal government between women and their health care professionals and deny women access to unbiased information so that they can make informed reproductive health and family planning decisions. No matter how the Administration chooses to characterize the proposal, it is a gag rule, plain and simple.

The Proposed Rule would also unfairly target – and unduly burden – Title X providers by requiring unnecessary physical and financial separation of Title X project activities from abortion-related activities. This requirement could force many Title X providers across Pennsylvania to eliminate services or shut down entirely, leaving many of Pennsylvania's most vulnerable citizens without access to essential reproductive health and family planning services. The Proposed Rule would inflict all these harms in the service of an extreme, counterproductive

[1] *See* 83 Fed. Reg. 25,502 (June 1, 2018).

agenda – cutting off government funds to Planned Parenthood, an organization that provides essential health care to millions of women, men, and families across this country.

We urge you in the strongest terms possible to reject the Proposed Rule and instead work to strengthen the Title X program so that comprehensive and scientifically-sound family planning services are available to all Pennsylvanians who need them. At minimum, this requires that our state's health care systems are not unduly disrupted and burdened, and that our state's medical providers are not hindered in upholding the fundamental principles of the doctor-patient relationship or the medical profession's code of ethics and best practices.

I. The Title X Program in Pennsylvania

Title X is the only federal statute that authorizes grants to clinics that provide family planning and health services to low-income and uninsured people who would otherwise lack access to such care. At its core, the Title X program is an affordable contraceptive provider and preventative care program that is vital to Pennsylvania's citizens.

Our commonwealth has the third highest number of Title X patients in the nation. In 2016, Title X funding provided services for 198,825 patients across the commonwealth – more than Texas (167,942), Florida (120,962), or Illinois (110,158). Title X clinics in Pennsylvania provide services to both men and women: in fact, 12 percent of all patients were male, higher than the national average of 10 percent.

Unlike many other states, Pennsylvania does not distribute Title X funds through a state agency. Rather, Title X grant money in the commonwealth is distributed by a network of four private, non-profit organizations who apply directly to the federal government. These organizations – AccessMatters, Adagio Health, Maternal and Family Health Services, Inc., and the Family Health Council of Central Pennsylvania – are each responsible for distributing Title X funds to clinics in different regions of the state. These four organizations – known as "Family Planning Councils" – also receive funding from the commonwealth and from private sources.

In 2017, Pennsylvania's four Family Planning Councils received $13,502,000 in Title X funding to support access to family planning and sexual health care services at 191 service sites throughout the commonwealth.[2] Those health care providers offer a range of essential preventive health services, including breast and cervical cancer detection, screening and treatment for sexually transmitted infections, HIV/AIDS testing, and contraception for thousands of low-income, uninsured, and underinsured individuals each year.[3]

This model has served Pennsylvania well, as the four Family Planning Councils are all uniquely positioned to evaluate the needs of their local communities and to ensure that Title X funds are utilized in the most effective and efficient way possible.

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[2] *See* National Family Planning & Reproductive Health Association, *The Title X Family Planning Program in Pennsylvania*, *available at* https://www.nationalfamilyplanning.org/file/impact-maps-2017/PA.pdf.

[3] *See id*.

Title X acts as a payer of last resort in Pennsylvania. Clinics attempt to identify other sources of funding for patient services, including other federal or state funding or private insurance, before relying on Title X grants. As a result, Title X truly is a lifeline for the patients who rely on it. Without the ability to obtain services through Title X-funded providers, many of these patients would have nowhere else to turn.

Planned Parenthood is the largest Title X provider in the commonwealth. While it only operates 13 percent of the centers funded by Title X in Pennsylvania (28 in total), it cares for 36 percent of all Title X patients. In many parts of the commonwealth, Planned Parenthood is the only available Title X family planning provider. For instance, in Bucks County – the fourth-largest county in the commonwealth – all of the Title X clinics are operated by Planned Parenthood.

II. The Proposed Rule Denies Pennsylvania Women, Men, and Families Access to Comprehensive, Medically-Accurate, and Nondirective Health Care.

If the Proposed Rule goes into effect, Pennsylvania women, men, and families will be denied access to medically-accurate, nondirective health care. The Proposed Rule strikes the requirement that pregnant women have an opportunity to receive information and counseling on all available options. Instead of receiving neutral, factual information, nondirective counseling, and referral for abortion when requested, Title X providers would be barred from offering women any affirmative support or assistance in seeking an abortion, even if requested.

The Proposed Rule ignores the simple fact that abortion *is* health care, and that denying women nondirective information about abortion – and referrals when requested – denies them the right to make their own reproductive choices. The Proposed Rule is in no way necessary to comply with the requirement that "[n]one of the funds appropriated [through the program] shall be used in programs where abortion is a method of family planning."[4] This prohibition has not been altered since it was enacted in 1970. The regulations as they currently stand, enacted with this requirement in mind, have been largely unaltered for eighteen years. The Proposed Rule goes beyond this long-standing prohibition, stretching it to absurd extremes. For instance, it prohibits a Title X provider from identifying which health care practitioners provide abortions on a list of alternate reproductive health care providers furnished at the patient's request.[5]

As a result, the Proposed Rule erases Title X's non-directive counseling requirement as well as its implied commitment to standards of quality medical care and competent medical counseling. A cornerstone of the Title X program is that "all pregnancy counseling shall be nondirective."[6] Medical professionals strongly support this requirement: The American College of Obstetricians and Gynecologists, the American College of Physicians, and the American Academy of Family Physicians all endorse nondirective options counseling as the appropriate

[4] 42 U.S.C.A. § 300a-6.

[5] Proposed Rule, 42 C.F.R. § 59.5(a)(5).

[6] Omnibus Consolidated Appropriations Act, 2018, Pub. L. No. 115-141 (2018).

role for providers when a patient is facing an unexpected pregnancy.[7] As such, the current regulations require pregnant women to be given the opportunity to be provided, upon request, "neutral, factual information and nondirective counseling on each of the options."[8] The Proposed Rule removes the requirement of "nondirective counseling" in the current regulation; in fact, it strikes the entire subsection. But removing the language from the regulation does not eliminate the statutory obligation; instead, it just highlights how far the Proposed Regulation strays from the legal requirement of nondirective pregnancy counseling.

In defending the Proposed Rule, HHS acknowledges that "the Title X program should help men, women, and adolescents make healthy and fully informed decisions about starting a family and determine the number and spacing of children." Implicit in that mandate, and inextricably linked to that purpose, is a recognition that these services are to be provided in the context of quality medical care. However, under the Proposed Rule, the family planning methods presented no longer need to be "medically approved," only "acceptable and effective."[9] The words "acceptable" and "effective" are not defined. Confusingly, the Proposed Rule also states that Title X projects "are not required to provide every acceptable and effective family planning method or service."[10] This language allows Title X providers to exclude methods of their choosing, which will almost certainly result in providers limiting their usage of highly-effective methods of contraception and family planning services.

Allowing the inclusion of less than highly-effective methods of contraception belies the scientific results of numerous studies which consistently show that devices such as Long Acting Reversible Contraceptives (failure rate of less than one percent) or pill-based birth control (failure rate of nine percent) are simply more effective methods of family planning than natural or fertility awareness-based methods (failure rate of 24 percent).[11]

These changes are inconsistent with the obligation of the medical community to provide complete disclosure of all options—including the legal and safe option of abortion under medically-appropriate circumstances—so that patients can provide informed consent for the chosen method of treatment. But instead of complete disclosure, the Proposed Rule would bar providers from presenting comprehensive information, causing patients to receive information that is incomplete and biased. As Title X is focused on pre-pregnancy care, providers must be able to refer patients to *all* high-quality providers in their area that meet their particular needs. The medical profession overwhelmingly agrees, as 110 health organizations—including the

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[7] *See* David Moss, Matthew Snyder, and Lu Lin, "Options for Women with Unintended Pregnancy," *American Family Physician* 91, no. 8 (April 15, 2015): 544-49, *available at* http://www.aafp.org/afp/2015/0415/p544.html; Rose Fife and Sarina Schrager, *The ACP Handbook of Women's Health* (Philadelphia: American College of Physicians, 2009), 508-515.

[8] 42 C.F.R. § 59.5(a)(5)(ii).

[9] 42 C.F.R. § 59.5(a)(1).

[10] *Id.*

[11] CDC, Effectiveness of Family Planning Methods, https://www.cdc.gov/reproductivehealth/contraception/unintendedpregnancy/pdf/Contraceptive_methods_508.pdf.

American Psychological Association and the Guttmacher Institute—submitted a comment letter dated May 16, 2018, raising similar concerns in opposition to the Proposed Rule.

III. The Proposed Rule Unduly Burdens Title X Providers and Puts at Risk the Access of All Pennsylvanians, Particularly Vulnerable Populations, to Affordable Family Planning Services.

HHS states that the purpose of the Proposed Rule is "to ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning and related statutory requirements." However, the true intent of the Proposed Rule is far different: the President has asserted that the true purpose of the Proposed Rule is to prevent Planned Parenthood from performing abortions.[12]

Courts have held that, under certain circumstances, the government may seek to persuade women not to have abortions. But as the Court of Appeals for the Seventh Circuit recently noted, "Women, like all humans, are intellectual creatures with the ability to reason, consider, ponder, and challenge their own ideas and those of others. The usual manner in which we seek to persuade is by rhetoric not barriers."[13] The Proposed Rule turns this simple observation on its head. It relies exclusively on barriers rather than persuasion, and it denies women the ability to make their own choices based on their own reasoning and beliefs.

To take just one example, the Proposed Rule prohibits Title X health centers from providing patients with the names of any health care providers who perform abortions, unless the patient "clearly states that she has already decided to have an abortion" and "of her own accord" specifically requests this information.[14] And even then, only a doctor may provide the relevant information to the patient, and the doctor cannot simply provide the woman with the name of health care providers who perform abortions.[15] Rather, the doctor may only "provide a list of licensed, qualified, comprehensive health service providers (some, *but not all*, of which provide abortion, in addition to comprehensive prenatal care)."[16] In providing this list, the doctor is prohibited from identifying *which* providers on it actually perform abortions.[17] So a woman who has already made up her mind and clearly stated that she wishes to have an abortion is apparently left to guess which providers on the list perform abortions, or is forced to contact every provider on the list until she finds one that will provide the health care service she has decided she needs and to which she is legally entitled.

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[12] *See*, *e.g.*, The Washington Times, *Trump presents plan for Title X changes to cut Planned Parenthood funding*, May 18, 2018, *available at* https://www.washingtontimes.com/news/2018/may/18/trump-changes-title-x-target-planned-parenthood/.

[13] *Planned Parenthood of Indiana & Kentucky, Inc. v. Comm'r of Indiana State Dep't of Health*, No. 17-1883, 2018 WL 3567829, at *18 (7th Cir. July 25, 2018).

[14] 83 Fed. Reg. 25531.

[15] *Id.*

[16] *Id.* (emphasis added).

[17] *Id.* ("The list shall not identify the providers who perform abortion as such.").

Given that it seeks to undermine—rather than faithfully implement—the requirements of Title X, it is unsurprising that the Proposed Rule works against the goal of providing access to family planning and reproductive health services to those who could not otherwise obtain them. In particular, the financial and physical separation requirements could cause many Title X clinics in Pennsylvania to either close or run at diminished capacity. As a result, many vulnerable women, men, and families would be at risk of losing access to affordable health care and family planning services due to Title X providers becoming unduly burdened in seeking to meet elusive logistical and administrative mandates.

The separation requirement would also apply to some of the broader and more vague prohibitions, including that Title X providers may not promote, support, or encourage abortion as a method of family planning. Title X providers are likely to have a difficult, if not impossible, task in ascertaining what activities would run afoul of these separation requirements. The Proposed Rule is therefore likely to have a significant prohibitory effect on a wide variety of otherwise-permissible activities paid for with non-Title X funds.

In the Commonwealth of Pennsylvania, stringent and meaningful separation is already statutorily required under Act 66 of 2006.[18] This includes:

- An independent auditor attesting that abortion-related activities are physically and financially separate from family planning activities funded by any family planning appropriation;
- All subgrantees who engage in abortion-related activities must provide to the grantees their board approved policies and procedures relating to the means and methods of separating abortion-related activities from family planning activities;
- Subgrantees must describe how they comply with the separation requirements.
- Grantees must make an annual inspection of all subgrantees conducting abortion-related activities to assure physical and financial separation from family planning activities. Grantees are required to attest, in writing, annually that the subgrantee met the physical and financial separation requirements for the state fiscal year; and
- Grantees must include the physical and financial separation requirements in every grant, contract or agreement with a subgrantee and shall develop guidelines for subgrantees regarding physical and financial separation.

The addition of new, conflicting rules as to what will be considered compliant presents unnecessary challenges to these providers. For example, a family planning provider would be required to "offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site."[19] Words like "comprehensive" and "robust" are insufficient to provide meaningful guidance to Title X programs. Although the Proposed Rule does cite examples, those examples only bolster the argument that a Title X grantee cannot know in advance whether it will be deemed

[18] Fiscal Code – Omnibus Amendments of 2006. P.L. 296, No. 66. (2006)

[19] 42 C.F.R. § 59.5(a)(12).

compliant. In effect, compliance standards have been transferred completely to the Secretary's discretion on a piecemeal basis.[20]

As a result of these mandates, Title X grantees would be forced to cease receiving Title X funds, drastically reorganize to comply with the Proposed Rule's administrative burdens, or open an entirely new health care facility. As such, the Proposed Rule would disproportionately harm the most disadvantaged populations in the commonwealth and leave them with no other options for high-quality family planning and sexual health care. This result runs directly counter to the purpose of Title X.

IV. The Introduction of a Qualitative Assurances Review by HHS Prior to Application Review by the Objective Merits Panel Appears Arbitrary and Capricious.

The Commonwealth has concerns that the Proposed Rule's review process may disqualify Title X applicants before they ever reach an unbiased review team. The result of the introduction of language to the grant award process may ultimately be an unfounded disruption of the heretofore stable and well-developed Title X system of care.

The Proposed Rule envisions an intrusive level of oversight into sub-grantee operations by requiring grant applications and all required reporting to include:

- Names and locations of subrecipients, referral individuals and agencies as well as services to be provided;
- Description of partnerships and collaborations with subrecipients; and
- Explanation as to how the grantee will ensure oversight and effectiveness of outcomes.[21]

These referral relationships and networks are critical in ensuring that low-income, uninsured, or underinsured patients have access to the full range of care they need from accessible providers across the safety net. Those outside providers, however, are also overburdened and unable to generate paperwork for or take on requirements from wholly separate Title X providers. Imposing Title X requirements on organizations that do not receive any Title X funding or have any responsibility for Title X providers would be impossible and only serve to cut Title X providers and their patients off from referrals. It would have a drastic impact on the ability of Title X providers to secure these referral arrangements and have a directly detrimental effect on patients' health and well-being.

The Proposed Rule significantly alters the program's grant review criteria. Since 1971 HHS issued awards based on seven specific factors:

1. The number of patients, and the number of low-income patients to be served;
2. The extent to which family planning services are needed locally;

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[20] *See*, *e.g.*, Proposed Rule at 42 CFR Part 59.15 ("The Secretary will determine whether such objective integrity and independence exist based on a review of facts and circumstances.").

[21] 42 C.F.R. § 59.5(a)(13).

3. The relative need of the applicant;
4. The capacity of the applicant to make rapid and effective use of the federal assistance;
5. The adequacy of the applicant's facilities and staff;
6. The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project;
7. The degree to which the project plan adequately provides for the requirements set forth in these [Title X] regulations.[22]

The reorganization and alteration of these award criteria under the proposed rule prioritizes the following;

1. The provision of "broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents) . . .";
2. Relative need and capacity to make rapid use partnering with non-traditional Title X partners.[23]

Access to complete care is critical for individuals who choose to terminate a pregnancy as well as those who wish to continue a pregnancy—making single-method providers' entry into the Title X network potentially dangerous and costly. The Proposed Rule shows a clear preference for organizations providing less effective methods of family planning by replacing the cautionary, caveat language of the current regulations (that organizations that only provide a single method of family planning *can still* participate in a Title X project as long as the entire project offers a broad range of family planning services) with a more permissive directive that "projects are *not required* to provide every acceptable and effective family planning method or service."

V. The Justifications Offered for the Proposed Rule are Inadequate.

Given the potentially devastating effect the Proposed Rule may have and the sharp departure that it represents from current practice, HHS's justifications are woefully inadequate. HHS does not explain in any meaningful way how the Proposed Rule comports with the stated goals of the Title X program. Congress enacted Title X "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services" and "to develop and make readily available information (including educational materials) on family planning and population growth to all persons desiring such information," among other reasons.[24] The Proposed Rule works directly against both goals, and the arguments offered in support do not begin to justify such a radical departure from a program's statutory purpose.

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[22] Office of Population Affairs. Program Requirements for Title X Funded Family Planning Projects. Version 1.0 (April 2014). https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf. Retrieved July 31,2018.

[23] 42 C.F.R. § 59.7.

[24] Pub. L. 91–572, § 2(1), 2(5) (Dec. 24, 1970).

Nor has HHS provided a sufficient economic impact analysis as to the Proposed Rules' costs to providers and patients, as required by Executive Orders 12866 and 13562. Although the Proposed Rule outlines various "Benefits and Protections," it ignores the costs to patients trying to obtain health care and to providers trying to comply with the new physical separation and administrative requirements. Although HHS explains that complying with the physical separation requirements would only cost $10,000 to $30,000 per site, the reality is that many Title X clinics would likely have to open a new facility to comply. Additionally, each clinic would have to demonstrate compliance with the new requirements for minor patients, requiring changes to electronic health records and increased staffing.

Of course, it is no surprise that the Proposed Rule is so inconsistent with the stated goals of Title X, given that its clear purpose is to eliminate funding for one specific organization. In December 2016, Mr. Trump stated that he was "committed to . . . [d]efunding Planned Parenthood as long as they continue to perform abortions."[25] But a candidate's rhetoric does not excuse an agency from complying with its legal obligations, and it certainly does not justify ignoring the expressed will of Congress by undermining the stated purpose of a statute the agency is charged with enforcing.

VI. The Proposed Rule Will Significantly Harm the Commonwealth of Pennsylvania.

The inevitable – and intended – result of the Proposed Rule is that many Title X clinics will close, while others will run at diminished capacity. Patients from these clinics will be forced to turn elsewhere for family planning services, including to state-funded programs. Some patients who are eligible will seek to enroll in Medicaid, known as Medical Assistance in Pennsylvania. Other Pennsylvanians will obtain services from Pennsylvania's Family Planning Services program, which was originally launched in 2008 as the Select Plan for Women. While both of these programs provide women and men with family planning services, neither can fill the void that will be created if Title X clinics are forced to close. In fact, these programs work most effectively in conjunction with Title X clinics, which already serve large numbers of participants in both programs. But if these clinics are forced to close, these patients – like those who receive services funded by Title X – will be forced to turn elsewhere. As a result, the Proposed Rule will cause harm that will extend far beyond those patients who receive services that are funded by Title X directly.

Other patients will experiences gaps in care or no care at all, leading to additional unintended pregnancies and negative health outcomes, including sexually transmitted infections, HIV/AIDS, and reproductive cancers. As a result, the Commonwealth will bear additional costs through Medical Assistance and other social service programs. Unintended pregnancies cost the Commonwealth $248.2 million in 2010,[26] and will cost far more in the future if access to Title X

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[25] *See* Letter from Donald J. Trump to Pro-Life Advocates (December 2016).

[26] See Guttmacher Institute, Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs for Pregnancy-Related Care (National and State Estimate for 2010), at 13 (Feb. 2015) at 13 (https://www.guttmacher.org/sites/default/files/report_pdf/public-costs-of-up-2010.pdf, retrieved 7/27/18).

clinics declines. In addition, many of these women and men will be unable to fully participate in the workforce, causing further economic harm to the commonwealth.

The Proposed Rule also fails to identify any inadequacies in Title X family planning care, any material failures of compliance, or any other evidence that might justify its proposed regulatory overhaul. HHS's current regulations and oversight powers already give it the capability to manage Title X grants and work effectively with the Title X network to best serve patients. Title X's primary issue today is lack of sufficient funding, not any purported problems with the rules governing this decades-old, well-functioning program.

VII. The Financial Implications of the Proposed Rule Will Be Significantly Burdensome.

While obviously designed to target those Title X-funded entities that also provide abortion services with non-Title X funds, the physical separation requirements would extend to a range of other activities which might be deemed by HHS to be tangentially associated with supporting or "promoting a favorable attitude toward" abortion. It is unreasonable to expect Title X-funded entities to be able to comply with these requirements, which will have the ultimate impact of excluding many highly qualified and trusted providers from being able to participate in the Title X program, thus significantly reducing access to care for countless patients who rely on Title X.

For instance, the Proposed Rule prohibits Title X projects and the entities that run them from making dues payments to "any group that, as a more than insignificant part of its activities" advocates abortion as a method of family planning "and does not separately collect and segregate funds used for lobbying purposes" and from disseminating any materials in any way that might promote a favorable attitude toward abortion.[27] Thus, in order for an organization running a Title X project to undertake activities that might fall within these broad and vague rules, the organization would have to pay such dues or disseminate such materials with non-Title X funds from a separate physical facility from the Title X project, apparently with separate entrances and exits, personnel, workstations, financial and record-keeping systems, and the like.

This effectively creates a complete bar on such activity for the provider; it is inconceivable that a provider would maintain a separate physical location with separate personnel and systems just to engage in activities as simple as writing a check to pay dues to a membership association with non-Title X funds or to disseminate information that might be construed as promoting a favorable attitude toward abortion.

When taken together, the totality of changes in the Proposed Rule presents a problematic reimagining of the Title X network of providers and subgrantees, in which the existing system and its benefits would be reconfigured to ensure the inclusion of providers which are not necessarily able to fully support and guide persons seeking comprehensive and highly effective family planning methods.

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[27] This requirement applies unless those organizations could—improbably—accomplish physical and financial separation for these activities.

Shifting the Title X program away from its original mission and intent would force long-standing expert providers out of the program, force health centers to close, and leave vulnerable Pennsylvanians without any access to care, resulting in increased rates of unintended pregnancies, sexually transmitted infections, and unsafe abortions.

These harms can be avoided if the Administration commits to increasing, rather than limiting, access to comprehensive, nondirective family planning services. Should you choose to pursue a policy that is consistent with the purposes of Title X by expanding the availability of family planning services, we stand ready to partner with you in that effort. We urge you to reject the unnecessary, harmful, and illegal Proposed Rule and to work with us to increase access to high-quality, affordable family planning care Pennsylvania and across the country.

Respectfully submitted,

TOM WOLF
Governor
Commonwealth of Pennsylvania

JOSH SHAPIRO
Attorney General
Commonwealth of Pennsylvania