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VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

**Re: Healthy Pennsylvania § 1115 Demonstration
Application**

Dear Sir/Madam:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to provide comments to Pennsylvania's proposed § 1115 demonstration, the Healthy Pennsylvania plan.

NHeLP recommends that HHS not approve the Healthy Pennsylvania application as requested. The application includes numerous provisions that clearly are not authorized by any law. We urge HHS to address these problems and require Pennsylvania to bring the proposal into a legally approvable form. We urge HHS to work with Pennsylvania to achieve a Medicaid expansion that will serve future Medicaid enrollees well, including those inside Pennsylvania affected by this proposal and those in other states who may pursue similar proposals. We request that HHS zealously enforce its stated policies and the legal limits of the Social Security Act's § 1115 demonstration project provisions, to ensure progress in Pennsylvania without opening the door to policies that ignore the fundamental nature of Medicaid as an entitlement program.

Second, we ask that before HHS takes action on this request, it take steps to address its own "stewardship of federal Medicaid resources." GAO, *Medicaid Demonstration Waivers: Approval Process Raises Cost Concerns and Lack of Transparency* at 32 (June 2013). As the GAO has concluded, "HHS's [budget neutrality] policy is not reflected in its actual practices and, contrary to sound management practices, is not adequately

documented....[T]he policy and processes lack transparency regarding criteria.” *Id.*

As addressed below, Pennsylvania’s § 1115 application should not be approved as filed for two major reasons. First, under the guise of an expansion, it is simply an impermissible, extreme, and profoundly harmful *reduction* of Pennsylvania’s existing Medicaid program. Second, the expansion component of the demonstration is illegal and unapprovable as requested.

I. Pennsylvania’s Proposed Changes to its Existing Medicaid Program are Illegal and Extremely Harmful

Although Pennsylvania describes this proposal as an attempt to move away from “one size fits all” coverage, the new plan is plainly an attempt to gut the state Medicaid plan. The true intention to slash Medicaid benefits is clear from the fact that both the low-risk and high-risk plans include benefit packages that are significantly worse than the existing state plan benefit. This is a move away from “one size fits all” to two sizes, both of which fit *worse* than the original size. If HHS approves these cuts to Pennsylvania’s Medicaid program, HHS will for the first time allow health reform to be associated to *worsened* health coverage for vulnerable individuals, and HHS will set a new lowest common denominator for other states to imitate. Bad faith is evidenced in numerous aspects of the proposal; for example, while extolling the virtues of employment for Medicaid recipients, the proposal simultaneously would cut the highly-successful Medicaid program supporting for individuals with disabilities who work.

HHS should not approve the changes to the current Medicaid state plan because, under the law, HHS cannot approve them. The statutory structure sets out two clear requirements for the Medicaid state plan benefit. First, it must include the mandatory services required under § 1902(a)(10)(A) and § 1905. Second, all services must be covered with sufficient amount, duration, and scope to reasonably achieve their purpose. Pennsylvania’s proposal violates both of these standards, and § 1115 demonstration authority cannot cure that illegality.

At the outset, it is unclear in the Pennsylvania proposal exactly what changes the state proposes to make to its traditional Medicaid program, which of those changes are to be pursued through this demonstration, and further, which of the possible changes are related to which waiver requests. Requests for waivers of core Medicaid standards cannot be approved through vague or undefined waiver requests – the pursuit and approval of such authority can only be conducted through a clear and transparent manner. This is the only way that stakeholders can actually comment on the waiver proposals. HHS should not entertain any waivers related to changes to Pennsylvania’s existing Medicaid program, nor approve any such changes, based on the current confused proposal. To even entertain such a proposal, HHS must require Pennsylvania to resubmit an application for full state and federal level comments.

For example, Table 3 indicates that Pennsylvania intends to maintain current limits on “family planning clinic” services in both the low and high risk benefit packages. However, it is not sufficiently clear from this language that the State intends to maintain current coverage of family planning services *and supplies*, whether or not they are provided in a “family planning clinic” setting. Under no circumstance should

Pennsylvania be permitted to waive freedom of choice protections for family planning, or reduce the amount, duration and scope of family planning services and supplies through this vague proposal.

Even if HHS entertained requests to change Pennsylvania's current Medicaid program through this waiver, they cannot be approved because they do not meet section 1115's requirements of an experimental purpose and promoting the objectives of the Medicaid Act. Pennsylvania's "experiment" amounts to reducing the health coverage of vulnerable Medicaid populations and then examining the individuals who go without coverage. It is a "shoot first, ask questions later" approach with no valid experimental methodology (Pennsylvania suggests it will tabulate "exception requests," which ignores the reality of the terrible outcomes of individuals who never request an exception, are denied an exception, whose care is delayed in the exceptions process, etc.) and even less valid experimental value. Moreover, our years of experience with exception procedures in other states verifies that they are ineffective markers of actual need, depending as they do upon knowledge of the exception by health care providers, a clear procedure for requesting the exception, and a willingness by the State utilization reviewers to apply the exception. Here, the results of this pointless and harmful "experiment" are easy to predict: vulnerable Medicaid enrollees will suffer.

The proposed changes to the traditional Medicaid program are also unsustainable under § 1115 because they do not promote the objectives of the Medicaid Act. The most fundamental purpose of the Medicaid program is to "furnish medical assistance" to the vulnerable categories of Medicaid related to "families with dependent children and of aged, blind, or disabled individuals". Pennsylvania's proposal would, contrary to the intent of Congress, slash benefits to the categories of coverage these foundational populations depend upon.

Put simply, Pennsylvania is attempting to cut its current Medicaid program. It does so through the guise of "expansion" because the state knows that it could not do so if the cuts were transparently proposed and reviewed through the normal state governance process. HHS should not be an accomplice to this attempt to use a § 1115 Medicaid expansion proposal as a Trojan horse, through which dramatic changes are made to the existing state Medicaid program serving low-income women and children and aged, blind and disabled individuals. In addition to blocking the intent of Pennsylvania to gut its current Medicaid program through "expansion," CMS should also specifically deny the "amount, duration, and scope" waiver request based on the vagueness of the request and proposed plans of the state.

II. Pennsylvania's Proposed Medicaid Expansion Is Not Legal or Approvable as Requested

A. Legal Authority for Premium Assistance

Pennsylvania proposes to conduct a § 1115 demonstration program to use *individual* market premium assistance to implement a Medicaid Expansion. It is our understanding that the state would rely on authority at § 1905(a) to do so. However, the statute and legislative history create serious questions about the validity of this claimed authority. Section 1905(a) defines "medical assistance" and, for the most part, is a listing of

services that can or must be included in this definition. By contrast, Congress has dealt with premium assistance in other, specific provisions of the Act. Congress has authorized states to conduct *group* or *employer* coverage premium assistance, which are unambiguously and carefully detailed in statute at §§ 1906 and 1906A. Notwithstanding two very recent policies from HHS (in regulatory and sub-regulatory guidance), there is no history of statutory or regulatory guidance for the purported § 1905(a) authority. Given the uncertainty of the statutory authority and the untested regulatory framework, we believe it is incumbent upon HHS to be extremely cautious and exacting in the approval of any such authority, and even more so for related waivers. HHS should hold tightly to the principles announced in its March 2013 Frequently Asked Questions document. And under these circumstances, HHS must also be unmistakably clear as to the waiver authorities being granted and their legal limits. In the context of Pennsylvania's proposal, HHS cannot even rely on Exchange standards (which are themselves already impermissibly low) as a minimum, because Pennsylvania proposes the possibility of using premium assistance for individual private plans outside of the Exchange. Under no circumstances should HHS approve discretion to allow premium assistance to such "private health insurance market" plans.

Pennsylvania has also requested authority to cover Medicaid expansion individuals with available employer coverage through its existing health insurance premium payment model (i.e., premium assistance) authorized under § 1906. However, Pennsylvania suggests it will "modify its current program for the newly eligible population, minus all Medicaid wraparound coverage."¹ It is unclear what waiver request Pennsylvania intends to achieve this through. In any event, coverage for employer sponsored premium assistance is already authorized under § 1906, and this is not waivable under § 1115 authority, which is limited to waiver of provisions in § 1902. Therefore, the requirements of § 1906, including for example, wrap-around of all cost-sharing and to only use premium assistance when cost-effective, must be strictly followed without exception. At any rate, CMS should not approve this request when it is not clear what the request actually is seeking.

B. Single State Agency

In addition to premium assistance authority concerns, Pennsylvania's request, as currently written, fails to ensure that the single state Medicaid agency will remain in charge of the Medicaid program for private option populations, as the Medicaid Act requires.² The application does not provide the general public or HHS with information and specifics establishing that the single state agency will continue to make administrative and policy decisions for the program. By law, the single state agency must be in control and accountable for developing and implementing Medicaid coverage. While Pennsylvania may not formally delegate away Medicaid authority, it in effect surrenders control over the majority of benefits for an entire category of enrollees. As currently proposed, Pennsylvania will not control many benefits package details, authorization criteria, and provider contracts and terms but will leave these to health plans. At the very least, HHS must require written agreements between the involved entities clearly delineating roles and responsibilities, with the ultimate authority and

¹ *Healthy Pennsylvania* proposal, page 54.

² Social Security Act § 1902(a)(5).

responsibility housed in the Medicaid agency. This would help assure consumer protections and enable ongoing reporting and monitoring, and would also address some of the GAO's conclusions that find HHS processes lack the supporting evidence required to justify deviations from historical requirements. GAO, *supra.* at 32.

C. Limits of § 1115 Waiver Authority

Section 1115 explicitly circumscribes waiver authority in Title XIX to requirements contained in § 1902.³ Anything outside of § 1902 is not legally waivable through the 1115 demonstration process. Despite this legal fact, Pennsylvania repeatedly requests waiver of requirements that lie outside of § 1902. These waiver requests, sometimes explicit and other times necessitated by their objectives, include attempts to skirt requirements in § 1903, § 1906, § 1916, § 1916A, § 1927, and § 1937. None of these waiver requests are permissible because the substantive requirement rests outside of 1902 and independently requires state compliance. In other words, any reference to the provision in section 1902, which could be waived, does not and cannot also waive the independent, freestanding requirements of these Medicaid Act provisions. Such waivers are also patently contrary to all of HHS' stated regulation and policy on premium assistance.⁴

Note finally that Pennsylvania cannot circumvent the requirements in § 1937 by requesting waiver of § 1902(k). Pennsylvania's proposal is predicated on receiving enhanced matching funds (100% FMAP in 2015) for its Medicaid Expansion population. However, under § 1903(i)(26), Pennsylvania cannot receive any matching funds for the Medicaid Expansion population that are not tied to coverage of § 1937 benefits. To put it simply, HHS cannot waive elements of § 1937 *and* pay enhanced FFP.

D. Premiums and Cost-sharing generally

Pennsylvania's § 1115 application contains numerous premium and cost-sharing features (each discussed below) which are not approvable under § 1115. Specifically, the proposals all repeatedly violate four core requirements for § 1115 demonstrations:

- As mentioned above, § 1916 and § 1916A are free-standing requirements lying outside of § 1902 which therefore cannot be waived through § 1115. Even assuming this isn't true, to the extent *any* waiver of cost-sharing in § 1916 could be legally permissible, it must be through compliance with the waiver requirements of §1916(f), the only appropriate legal channel for such waivers. Pennsylvania attempts to waive cost-sharing requirements in §1916 through § 1115 without following the § 1916(f) requirements. Section 1916(f) only applies to cost-sharing, thus even if Pennsylvania

³ Social Security Act § 1115(a)(1).

⁴ See 42 C.F.R. § 435.1015(a)(2), requiring the agency to furnish "all benefits for which the individual is covered under the State plan that are not available through the individual health plan." In the preamble to this regulation, HHS clearly explained that it "will only consider demonstrations under which states make arrangements with the health plan to provide wraparound benefits and cost sharing assistance." 78 Fed. Reg. 42186. See *also* "Medicaid and the Affordable Care Act: Premium Assistance," HHS FAQ, March 29 2013, page 2, stating that "HHS will only consider proposals that ... [m]ake arrangements with the QHPs to provide any necessary wrap around benefits and cost sharing."

complies with § 1916(f), the legal prohibitions on premiums for individuals below 150% FPL are still *never* waivable.

- An § 1115 demonstration is precisely that, a demonstration. Pennsylvania's requests for §1115 authority around premiums and cost-sharing are not approvable because, as proposed, and given the well-known results of studies on cost-sharing and premiums, they will not test anything.⁵ For example, one of the principal features Pennsylvania seeks to waive – premiums for low-income enrollees – has already been tested repeatedly and consistently shown to *depress* enrollment – including for the very population of adults that is the focus of the Pennsylvania proposals.
- Section 1115 demonstrations must also be “likely to assist in promoting the objectives” of the Medicaid program. The objective of the Medicaid program is to *furnish* health care to low income individuals. Many of the premium and cost-sharing elements in Pennsylvania's proposal cannot be approved because they, to the contrary, *reduce* access to care. The Medicaid Act, particularly § 1916A, already provides States like Pennsylvania with a great deal of flexibility to impose premiums, cost sharing, and similar charges. Yet, Pennsylvania and other states seek to run past these options, never using them, to implement proposals that the research has already established are harmful to low-income people – provisions that will clearly result in interrupted care, lost opportunities, and churning.
- Cost sharing must adhere to § 1916(f).

E. Premiums

Pennsylvania has requested § 1115 authority for premiums for individuals above 100% FPL. HHS cannot legally approve these premiums and, as a matter of policy, should not approve them. Congress has been specific about its objectives. Medicaid law generally prohibits premiums for individuals below 150% FPL.⁶ There is no broadly applicable exception to this general prohibition. The possibility for a consumer to obtain a reduction of the premium for complying with prevention requirements does not cure the illegality of otherwise imposing the premium. Nor would the legal problem be cured by allowing the full premium to be waived or a “hardship waiver.” HHS cannot legally approve these requests.

Aside from the clear legislative language and intent to generally prohibit premiums below 150%, HHS also lacks authority to waive this requirement with § 1115. Premium limits set out in § 1916 cannot be waived under § 1115, which only allows waiver of provisions in § 1902.

⁵ For an extensive discussion of the literature around premiums and cost-sharing, see David Machledt and Jane Perkins, *Medicaid Cost-sharing and Premiums* (March 2014), available at <http://www.healthlaw.org/publications/browse-all-publications/Medicaid-Premiums-Cost-Sharing#.UzneLoX3IX5>.

⁶ See Social Security Act §§ 1916(c), 1916A(b)(1)(A). There are very limited exceptions to this rule, for certain populations, that are not broadly applicable to the Medicaid expansion population. See, e.g., § 1916(d).

Furthermore, premiums below 150% FPL are also unapprovable because, given the well-established studies on the impact of premiums on low-income people, there is no experimental value to premiums, as required by §1115(a). This is why Congress generally prohibits them for low-income Medicaid populations (who, by definition, cannot afford life's basic necessities, much less an insurance premium).⁷ For example, in 2003, Oregon experimented with charging sliding scale premiums of \$6-\$20 and higher copays on some groups in an already existing § 1115 demonstration for families and childless adults below poverty. Nearly *half* the affected demonstration enrollees dropped out within the first nine months after the changes.⁸ Another multi-state study of low-income health programs found that premiums amounting to 1% of family income reduce enrollment by nearly 15%, while premiums set to 3% of family income cut enrollment in half.⁹ The result of premiums on low-income individuals has no experimental value because we already know the outcome, and the outcome is clearly negative.

Based on this evidence, the proposed premiums must also be denied because they fail to promote the objectives of the Medicaid Act, as also required under § 1115 law. A policy which disenrolls half of the population cannot plausibly help “furnish medical assistance.”

We also note that mandatory pre-payment of premiums likewise lacks any legal basis, has no experimental value, and fails to promote the objectives of the Medicaid Act.

Most alarmingly, Pennsylvania's proposal would also be illegal because of the consequences for failure to pay the premium. There is no authority in Medicaid for termination for non-payment of premiums for this low-income population, and no authority for “lockouts” after termination for any population. If, contrary to our recommendations and the law, HHS approves any premiums, HHS must eliminate the termination and lockout provisions to reduce the harm inflicted by the illegal premiums – harm which will cause personal suffering and form the basis of legal challenges. This termination policy, when combined with the attempt to eliminate retroactive coverage, means that many terminated individuals will go without coverage *exactly* when they try to access the health system (e.g., after an accident or acute event), which will harm providers and promote “cost-shifting.” Considering that one of Pennsylvania's central stated purposes for its § 1115 requests is to increase continuity and *reduce* churn, it is a glaring contradiction for Pennsylvania to pursue this termination (and lockout) for non-payment policy which is a clear churn *accelerator* – we noted earlier that premiums at similar income levels have been found to cut enrollment in half.¹⁰

Cost-sharing and premiums are bad health care policies and we broadly oppose them because of the harm they cause consumers. But *some* forms of cost-sharing, while not good policy, are at least permissible under law. Pennsylvania's requested premiums are both bad policy *and* illegal. If Pennsylvania is insistent on pursuing a flawed theory of

⁷ Premiums have only been permitted in exceptional categories, such as for states expanding coverage to workers with disabilities.

⁸ Machledt & Perkins, *supra* n. 7, at 1 (citing Bill J. Wright et al., *The Impact of Increased Cost Sharing on Medicaid Enrollees*, 24 Health Affairs 1106, 1110 (2005)).

⁹ *Id.*, at 15 (citing Leighton Ku and Teresa Coughlin, *Sliding-Scale Premium Health Insurance Programs: Four States' Experiences*, 36 Inquiry 471, 476 (Winter 1999-2000)).

¹⁰ *Id.* (citing Leighton Ku and Teresa Coughlin, *Sliding-Scale Premium Health Insurance Programs: Four States' Experiences*, 36 Inquiry 471, 476 (Winter 1999-2000)).

“personal responsibility,” HHS must work with the state to transform the illegal premium scheme into a system of permissible nominal cost-sharing, including full compliance with related regulations, such as those concerning non-enforceable cost-sharing.

We note finally, that Pennsylvania’s proposed Medicaid premium amounts actually exceed the Exchange maximum limit of 2% of income for the lowest income populations subject to the premium.

F. Monthly Cost-sharing Charge

Pennsylvania has requested authority to bill consumers for their copay debt on a monthly basis. This proposal should be denied for a number of reasons. First of all, it runs completely contrary to the legal design of Medicaid cost-sharing, which authorizes *states* to choose whether to establish copays and set their amounts, and authorizes *providers* to charge copays, enforce or forgive copay obligations, and hold a debt. Pennsylvania’s proposal fails to explain how the legal role of the provider would be carried out under the state-based cost-sharing system. For example, the statute requires that nothing in cost-sharing enforcement “shall be construed as preventing a provider from reducing or waiving the application of such cost sharing on a case-by-case basis.”¹¹ Therefore, for *every* copay charge in Pennsylvania’s monthly debt account for *every* individual, the state would be required to offer the provider an opportunity to waive the copay. Nothing in Pennsylvania’s proposal addresses how this would be done, nor could it be done without a burdensome administrative system. The Congressional design of Medicaid cost-sharing was never meant to include states charging copays, and this is not accidental: only the provider is in the position to understand the clinical needs of the patient, the importance of the treatments, the socioeconomic challenges the patient faces, the patient’s history of treatment compliance, the “on the ground perspective”, etc., while the state Medicaid agency has no such perspective.

In addition, HHS cannot approve this request unless Pennsylvania confirms it will not violate Medicaid law with respect to copay debt liability. Under this system, Pennsylvania would need to have a purely administrative role, tracking and charging copays on behalf of providers, because under the law enrollees can only have a debt liability to providers, not a state. Therefore, Pennsylvania could not pursue alternative means to enforce the debt liability, such as garnishing wages, liens, withholding tax refunds, or other debt collection mechanisms.

Pennsylvania’s monthly cost-sharing system also cannot be approved because it fails on waiver authority. As mentioned earlier, provisions in § 1916 lie outside of § 1902, and thus cannot be waived under § 1115 authority. Even assuming § 1115 did allow such a waiver, in order to change the entire function of § 1916 cost-sharing through § 1115, Pennsylvania would need to comply with the stringent requirements § 1916(f). HHS certainly cannot approve any waiver of § 1916, and implement a monthly cost-sharing system, until Pennsylvania explains how it will comply with § 1916(f). Note: All of the population groups being affected here are described in the Medicaid Act; thus,

¹¹ Social Security Act § 1916A(d)(2). See also 42 C.F.R. § 447.52(e)(3).

CMS cannot resort to its purported “expenditure authority” to approve this illegal request.

G. Wrap-around Generally

Pennsylvania’s proposal includes an extraordinarily broad waiver request “to permit the Commonwealth not to cover wraparound services” in the private option. As a matter of law, this request should be denied because it would violate CMS regulations and guidance which *require* wrap-around. Any guidance implementing § 1905(a) authority should not be within the reach of § 1115 waiver, since § 1905(a) lies outside of § 1902. Furthermore, such a broad waiver is also not legally approvable under § 1115 authority because it ignores the fact that the Medicaid wrap-around requirements flow from numerous statutory provisions, while, again, *only* provisions in § 1902 can be waived through § 1115 authority. In our analysis of specific services below, we also highlight the reasons that these wrap-around waivers also must be denied because they have no experimental value and fail to promote the objectives of the Medicaid Act, as required under § 1115.

CMS should also deny this wrap-around waiver because, even if all of the various pieces of it were legal, it is completely vague and overbroad. If Pennsylvania wants an exception to a specific Medicaid requirement, it must *specifically* request waiver of that provision, which CMS can then review. CMS cannot delegate any authority or discretion to Pennsylvania to freely waive on a broad topic across all Medicaid provisions.

H. Copayments for Non-emergent ER Use

Pennsylvania has requested §1115 demonstration authority to charge heightened copays of \$10 per visit for non-emergent use of the ER. Such copays are only permissible for individuals above 150% of FPL; individuals below 150% can only be charged nominal copayments.¹² Recent regulations provide states with the flexibility to charge as much as \$8 as the “nominal” amount for non-emergent ER visits for populations below 150% FPL.¹³ Therefore, CMS cannot approve the request to impose a \$10 copay. The law is clear; the policy, heavily studied; there is role for an experiment (and if there were, it would need to occur pursuant to § 1916(f)).

Section 1115 cannot be used to approve such a waiver for a number of reasons. First, the cost-sharing limits in § 1916 cannot be waived under § 1115, which only allows waiver of provisions in § 1902.

Additionally, a higher copay would serve no valid demonstration purpose nor promote the objectives of the Medicaid Act. Cost-sharing has already been shown to be a barrier to low-income populations accessing care.¹⁴ CMS itself, in a recently released bulletin

¹² Social Security Act §§ 1916(a)(3), 1916(b)(3).

¹³ 42 C.F.R. § 447.54.

¹⁴ General evidence suggests that increased copays may discourage unnecessary *and* necessary ED care, especially for low-income enrollees. See J. Frank Wharam et al., *Emergency Department Use and Subsequent Hospitalizations among Members of a High-Deductible Health Plan*, 297 JAMA 1093, 1098 (2007) and Joe V. Selby et al., *Effect of a Copayment on Use of the Emergency Department in a Health Maintenance Organization*, 334 New Eng. J. Med. 638 (1996). Evidence specific to Medicaid and CHIP

on best practices to reduce unnecessary ED use, recognizes that strategies like expanding access to primary care or providing health homes for frequent ED users may be effective, but suggests that increased copays for nonemergency use are unproven and problematic to implement fairly.¹⁵ A heightened copay, therefore, offers no positive experimental value and would undermine the objective of the Medicaid Act to furnish medical assistance for enrollees. We would ask CMS not to undermine this 3-month old guidance document by allowing Pennsylvania to impose these copayments.

We note that the individuals subject to this charge may be extremely poor, and an \$8 charge would already give them “skin in the game.” In particular, it strains credulity to believe that a \$10 copay would achieve any significant experimental objective not achieved under the existing \$8 authority.

We also urge HHS to require Pennsylvania to explain how it will ensure compliance with statutory requirements that, prior to charging any copay for non-emergent use of the ER, there must be an “actually available and accessible” alternate care option and that the facility must provide notice that the care to be provided is non-emergent care subject to additional charges, identify the alternative care option, and provide the enrollee with a referral.¹⁶

I. Non-emergent Medical Transportation

Pennsylvania has requested permission to not provide non-emergent medical transportation (NEMT) for private option enrollees. However, Medicaid requires coverage of NEMT.¹⁷ This is a core Medicaid requirement, applicable to all enrollees, which ensures beneficiary access to care.

Approving premium assistance without NEMT would contradict CMS’ existing regulations and policy on premium assistance, which require states to furnish “all benefits for which the individual is covered under the State plan that are not available through the individual health plan.”¹⁸ In guidance, CMS has clarified that Medicaid enrollees in any state premium assistance arrangement “remain Medicaid beneficiaries and continue to be entitled to all benefits and cost-sharing protections.”¹⁹ If CMS

finds that there is no discernible effect on ED utilization (emergency or nonemergency) for Medicaid enrollees. See Karoline Mortensen, *Copayments Did Not Reduce Medicaid Enrollees’ Nonemergency Use of Emergency Departments*, 29 Health Aff. 1643 (2010) and David J. Becker et al., *Co-payments and the Use of Emergency Department Services in the Children’s Health Insurance Program*, 70 Med. Care Res. Rev. 514–529 (2013).

¹⁵ CMS, *Reducing Nonurgent Use of Emergency Departments and Improving Appropriate Care in Appropriate Settings* (Jan. 16, 2014), <http://www.medicare.gov/Federal-Policy-Guidance/downloads/CIB-01-16-14.pdf>; see also Wash. State Health Care Authority, *Emergency Department Utilization: Assumed Savings from Best Practices Implementation* (2013).

¹⁶ Social Security Act § 1916A(e)(1).

¹⁷ See 42 C.F.R. § 431.53; CTRS. MEDICARE & MEDICAID SERVS., STATE MEDICAID MANUAL § 2113.

¹⁸ 42 C.F.R. § 435.1015(a)(2). In the preamble to these regulations, HHS clearly explains that it “will only consider demonstrations under which states make arrangements with the health plan to provide wraparound benefits and cost sharing assistance.” 78 Fed. Reg. 42160, 42186 (July 15, 2013).

¹⁹ See DEP’T HEALTH & HUMAN SERVS., MEDICAID AND THE AFFORDABLE CARE ACT: PREMIUM ASSISTANCE FAQ (Mar. 2013) [Hereinafter PREMIUM ASSISTANCE FAQ], available at <http://medicaid.gov/Federal-Policy-Guidance/Downloads/FAQ-03-29-13-Premium-Assistance.pdf>.

dutifully applies regulations and its own guidance, it could not approve premium assistance which did not include NEMT.

HHS also cannot legally approve a waiver of NEMT under § 1115 authority. Under the law, a request must have a valid experimental purpose and promote the objectives of the Medicaid Act to be approved under § 1115 authority. As a threshold matter, the Pennsylvania request to waive NEMT should not be approved because it is not referenced in any of the demonstration “hypotheses” listed in the application (starting on page 15). It is not remotely enough for Pennsylvania to merely request a § 1115 waiver and aver it is for an experiment. The state must delineate a clear and demonstrative hypothesis and explain the experimental design and methodology by which the hypothesis will be evaluated. Pennsylvania offers none of these for the NEMT waiver request, and in doing so fails to meet the minimally necessary threshold for HHS to even consider the request, much less approve it.

It is most likely that Pennsylvania included no such hypothesis because in reality none is tenable. No hypothesis or evaluation is necessary to understand the consequence of *not* providing transportation services to low-income individuals, some of whom live in rural areas with no public transportation; it is patently obvious their access to care will be harmed. There simply is no potential experimental value to waiving NEMT. Furthermore, since reducing transportation will only reduce access to medical coverage, it does not promote the objectives of the Medicaid Act, another requirement in § 1115 which any NEMT waiver would fail to meet.

J. Mandatory Family Planning Services and Supplies

In addition to a harmful waiver of freedom of choice protections that would restrict access to family planning *providers* (addressed in the next section), Pennsylvania also appears to be requesting an unprecedented waiver of mandatory Medicaid family planning *services*, and its obligation to provide those services as wrap-around benefits to the extent they are not covered by a private option plan. The State’s list of proposed waivers (Table 11) is so lacking in specificity that it is difficult to ascertain the State’s intention, but the application briefly states elsewhere that:

“The Department has requested waivers for all wraparound services, including non-emergency transportation *and family planning services* (to the extent such services are not covered under the private plan)”,²⁰ and

“The proposed waiver of *family planning services* only applies to the Private Coverage Option. Private market health insurance plans participating in the Private Coverage Option must cover family planning services through the federal Essential Health Benefit requirement.”²¹

The imprecision and uncertainty of this waiver request should alone be grounds for HHS to deny the request; waivers must be explicitly requested to be granted. More importantly, such a waiver is impermissible under the law and would constitute a clear

²⁰ *Healthy Pennsylvania* application, page 71.

²¹ *Healthy Pennsylvania* application, page 141.

violation of recent HHS guidance regarding states' obligation to provide private option enrollees with all required Medicaid benefits and protections.

Family planning services and supplies (FPSS) are a longstanding mandatory Medicaid service that states must cover for all eligible individuals in their state plans.²² More importantly, § 2303(c) of the Affordable Care Act added FPSS – *in addition to* the Essential Health Benefits requirements – as a specifically required service in the § 1937 “Alternative Benefits Package” which every Medicaid expansion must cover. Under the statute, Pennsylvania’s Medicaid expansion – whether through a private option or not – *must* cover FPSS. The EHB requirements for covering preventive services, while important, do not legally absolve the State from complying with the Medicaid FPSS requirements in statute and regulation. This requirement in § 1937 lies outside of § 1902, and therefore cannot be waived under § 1115 authority. And, as mentioned earlier, a waiver of § 1902(k) does not change the fact that § 1903(i)(26) only authorizes matching funds for Medicaid expansion coverage which complies with § 1937.

Because FPSS are a mandatory benefit that cannot legally be waived in this context, they must be provided as wrap-around coverage to the extent such services and supplies are not sufficiently covered in private option plans. Pennsylvania claims in its application that FPSS are provided sufficiently through the Essential Health Benefits (EHB); however, this assumption is not warranted and cannot justify a waiver of wraparound services. There may be circumstances now or in the near future under which Medicaid family planning services and supplies coverage is more robust than what is covered in a private option plan.²³ In those circumstances, Medicaid beneficiaries must be able to access the benefits to which they are entitled.

A waiver of the FPSS coverage requirement, so clearly and explicitly applied by Congress for all Medicaid coverage packages, also cannot be waived because such a waiver has no experimental value and would not promote the objectives of the Medicaid Act, as required by § 1115. What Pennsylvania proposes here is a simple benefits cut, not an experiment, and more than one court has noted that § 1115 is not an appropriate way to implement such cuts. *See, e.g., Newton-Nations v. Betlach*, 660 F.3d 370 (9th Cir. 2011).

K. Freedom of Choice

Pennsylvania’s request to limit access to family planning providers also violates federal law and should be soundly rejected. The application requests that HHS waive § 1902(a)(10)(A) and 1902(k) to “permit the Commonwealth not to cover all family planning *providers*.”²⁴ This request is unclear because neither § 1902(a)(10)(A) nor 1902(k) related to network or delivery systems or providers. Additionally, the State seeks to waive § 1902(a)(23) in its entirety without excepting § 1902(a)(23)(B), which HHS has rightfully preserved in other recently approved waivers (e.g. Iowa, Arkansas).

²² Social Security Act § 1905(a)(4)(C).

²³ For example, a lack of enforcement and clarity about the limits of “medical management techniques” permissible under Federal regulations have led to insurer practices that deny coverage of certain contraceptive methods in spite of the broad contraceptive coverage requirement embedded in the EHB.

²⁴ *Healthy Pennsylvania* application, page 96.

Medicaid law guarantees beneficiaries the freedom to receive covered family planning services and supplies from qualified providers of their choice. Allowing Pennsylvania to waive this requirement would impermissibly restrict beneficiaries' access to providers and undermine this core protection. HHS and a number of district and federal circuit courts of appeal have consistently made clear that states must cover family planning services and supplies provided by any qualified provider, including out-of-network providers.²⁵ We therefore urge HHS to deny the State's request and require it to allow beneficiaries to go outside of plan networks for family planning services without cost-sharing or referrals, *regardless of the availability of in-network providers*. To this end, HHS should make clear that any waiver of § 1902(a)(23) (or § 1902(a)(10)(A) or (k)) does not include a waiver of § 1902(a)(23)(B) requirements.

L. Work Search Incentives

We commend Pennsylvania for its March 5, 2014 letter retracting its proposal for work search requirements as a condition of eligibility.

While the newly proposed work search incentives policy is an improvement over the mandatory work search policy – both in terms of law and policy – we still do not believe it is approvable. The purpose of the Medicaid program, according to the Medicaid Act itself, is to “to furnish medical assistance on behalf of” eligible populations.²⁶ Medicaid dollars cannot be used for other purposes. More specifically, § 1115 authority, which sets “promoting the objectives” of the Medicaid Act as a prerequisite for approval, clearly cannot be used to authorize a work search incentivization scheme. To the extent Pennsylvania relies on evidence showing “working people are healthier” to justify this waiver request, we note that the data does not necessitate causal connection (i.e., the data may only confirm the common sense proposition that healthy people are more likely to work). More importantly, allowing Medicaid funding to be diverted to such tenuous connections would mean that a state could use Medicaid money to promote *anything* remotely correlated to improved health. This is a dangerous and wholly unprecedented “Pandora’s box” of problems to open. CMS should deny the work incentives request because it is an illegal and dangerous precedent.

Setting aside the facial illegality of a work search incentive policy, we urge HHS to deny this approval because of the serious problems it will have as implemented. Even with good intentions, it would be extremely difficult for Pennsylvania to implement this requirement in a way that did not discriminate against individuals who cannot work because of their chronic or temporary health status. These individuals will essentially be forced to pay higher copays and premiums because of their illness or disability. This is patently unfair and will lead to suffering for individuals who will pay medical expenses with their food budget or attempt to work when it is dangerous for them to do so. For Pennsylvania and HHS, the legal liability associated with the discrimination on the basis of health condition, health status, or disability will be costly.

M. Federally qualified health centers/Rural health clinics

²⁵ See CTRS. MEDICARE & MEDICAID SERVS., STATE MEDICAID MANUAL § 2088.5.

²⁶ Social Security Act § 1901.

We commend Pennsylvania's decision to comply with Medicaid standards for FQHC and RHC access, as required by Medicaid law under § 1902 and § 1937.

N. Retroactive & Point-in-time Eligibility

Medicaid requires states to provide retroactive and point-in-time coverage for enrollees.²⁷ Pennsylvania has requested § 1115 demonstration authority to waive this requirement. This waiver should not be allowed because there is no demonstrative value to the request. The entirely predictable result will be: (1) more low-income individuals experiencing medical debt collections and bankruptcy; (2) more providers – especially safety net hospitals – incurring losses; and (3) more individuals experiencing gaps in coverage when some providers refuse to treat them because the providers realize they will not be paid retroactively by Medicaid. This policy has dubious hypothetical benefits and very concrete harms. For these same reasons, the § 1115 demonstration should not be approved because this does not promote the objectives of the Medicaid Act.

Pennsylvania's request to waive retroactive coverage also must be denied because the state has entirely failed to propose any demonstration "hypotheses" addressing the experimental value of such a waiver. It is not remotely enough for Pennsylvania to merely request a § 1115 waiver and aver it is for an experiment. The state must delineate a clear and demonstrative hypothesis and explain the experimental design and methodology by which the hypothesis will be evaluated. Pennsylvania offers none of these for the retroactive coverage waiver request, and in doing so fails to meet the minimally necessary threshold for HHS to even consider the request, much less approve it. We note in particular how glaring this omission is in light of Pennsylvania's poorly designed hypothesis around uncompensated care (Hypothesis #1.5 on page 16). Pennsylvania tries to justify its hypothesis comparing a private option expansion to no Medicaid expansion, and uses this to predict a "decrease" in uncompensated care. However, it is clear that if Pennsylvania compared the private option to a normal Medicaid expansion, as authorized by Congress under the law, uncompensated care would remain the same (at best) generally, and would clearly *increase* if a waiver of retroactive coverage was added. Pennsylvania's proposed waiver of retroactive coverage is unsupported by any hypothesis, and in fact contradicts other hypotheses if they were adequately designed.

We note that Pennsylvania's proposed policy objective in requesting waiver of retroactive eligibility is to coordinate eligibility with the Marketplace, which can effectuate eligibility on the first day of the following month (and some cases the first day of the second following month). However, this is a poor policy. And in fact, the gaps in coverage it would *create* are a glaring contradiction to the purported purpose for Pennsylvania's demonstration, which is to *prevent* gaps created by churn.

O. Appeals

²⁷ Social Security Act § 1902(a)(34); 42 C.F.R. § 435.914 (redesignated at §435.915 in 77 Fed. Reg. 17143).

Pennsylvania’s application proposes an “appeals” system which does not comply with the U.S. Constitution or Medicaid due process and cannot be approved in the current form by HHS. Regardless of the fact that Pennsylvania may enroll some Medicaid-eligible individuals into private market coverage via premium assistance, these individuals remain Medicaid enrollees and subject to Medicaid due process protections.

While Pennsylvania indicates it will retain the Medicaid appeals process for “appeals relating to determinations of eligibility decisions and plan placement,” it proposes to rely on the QHP process for appeals “relating to coverage determinations and provider access decisions”.²⁸ However, Medicaid enrollees must have access to the Medicaid appeals system, and the unique features of that system (including continued benefits), for all Medicaid covered services. It might be appropriate for Pennsylvania to create an internal plan appeals process, so long as it does not interfere with the individual’s right to obtain a timely decision, generally within 90 days of the date of the request or within days in expedited circumstances. For any enrollee in Medicaid – whether in premium assistance or not – core Medicaid due process protections such as the right to notice, fair hearing, and aid paid pending appeal, must be preserved and can never be waived by HHS. This foundational principle should not be moved.

This feature of Pennsylvania’s proposal is also unapprovable because, even if it *were* Constitutionally permissible, no waiver authority is sought to implement it among Pennsylvania’s 24 waiver requests. No request for waiver authority can be approved unless it is explicitly and specifically requested.

P. Prior Authorization

Pennsylvania has requested a waiver of § 1902(a)(54) to “permit the Commonwealth to require that requests for prior authorization for drugs be addressed within 72 hours, rather than 24 hours,” as is required under § 1927(d)(5)(A).²⁹ Recent Medicaid regulations confirm that Medicaid expansion benefit packages (the ABP) are subject to § 1927 requirements for drugs that are covered by the ABP.³⁰ Although § 1902 does *reference* § 1927, such reference does not change the fact that § 1927 places *independent requirements* on the ABP. The requirements in § 1927 lie outside of § 1902 and are thus not waivable under section 1115 of the Act. Pennsylvania cannot waive, and must comply with, the § 1927 requirement to respond to prior authorization requests in 24 hours for drugs covered under the ABP which are subject to section § 1927. These requirements, set by Congress, are reasonable and necessary, given the importance of commencing and maintaining medication regimens as soon as possible after the prescription is written (whether there is an emergency or not). We also encourage HHS to assess the health and safety repercussions of allowing 72 hour delays in medications that doctors are prescribing for immediate use.

Q. Hypotheses and Evaluation

²⁸ *Healthy Pennsylvania* application, page 51.

²⁹ *Healthy Pennsylvania* application, page 95.

³⁰ 42 C.F.R. §440.345(f).

Although the Pennsylvania proposal includes numerous hypotheses to be tested, we believe that few of them present a valid experiment to be tested, and none include the specificity of hypothesis and evaluation needed for approval. For example, Pennsylvania's "Potential Methodology, Metrics, and Data Sources" for administrative costs (on page 15) states:

"Determine Demonstration group and compare the administrative costs of that group to the group's administrative costs in previous years. Alternatively, compare to the administrative costs of a non-Demonstration control group."

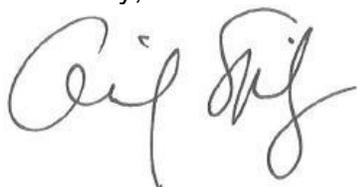
This does not tell the reader anything of value. Pennsylvania is undecided between two methodologies, and even each of these suggestions, in turn, is completely vague with respect to what the demonstration groups would be, what the costs would be, how they would be compared, etc. This is simply not enough information to remotely assess whether the hypothesis – even *assuming* it were valid – will be tested in any meaningful way likely to produce any lessons.

In all cases, the hypotheses must be tested using a well-designed experiment followed by comprehensive analysis. HHS should not approve these proposals until Pennsylvania has clarified the methodologies that will be used to conduct meaningful demonstration analysis. HHS also should not approve these proposals until it has clarified with the state and the public its own rule for oversight, monitoring and enforcement during the life of the proposal. We urge HHS to scrutinize this report carefully. As we have noted, the GAO has published repeated and serious concerns with HHS's failure to enforce its policies regarding cost-effectiveness. See GAO, *Medicaid Demonstration Waivers: Approval Process Raises Cost Concerns and Lack of Transparency* (June 2013) (citing previous reports).

Conclusion

In summary, we have numerous concerns with the legality of Pennsylvania's § 1115 demonstration application, as proposed. Please know that we fully support the use of § 1115 of the Social Security Act to implement true experiments. We strongly object, however, to any efforts to use § 1115 to skirt essential provisions that Congress has placed in the Medicaid Act to protect Medicaid beneficiaries and ensure that the program operates in the best interests of the population groups described in the Act. We urge HHS to address our concerns prior to issuing any approval. If you have questions about these comments, please contact Leonardo Cuello (cuello@healthlaw.org). Thank you for consideration of our comments.

Sincerely,



Emily Spitzer,
Executive Director