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VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–2370–P
P.O. Box 8016, Baltimore, MD 21244–8016

Attention: CMS–2370–P
Medicaid Program; Payments for Services Furnished by Certain Primary Care Physicians and Charges for Vaccine Administration Under the Vaccines for Children Program

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. NHeLP provides technical support to direct legal services programs, community-based organizations, the private bar, providers and individuals who work to preserve a health care safety net for the millions of uninsured or underinsured low-income people. With the implementation of the new health reform law, and millions of newly insured individuals entering the health system, assuring access to care will be a key concern. Medicaid enrollees already have challenges accessing primary care providers in some areas, so it is critical that access be improved in anticipation of the growing Medicaid population. We appreciate the ability to provide comments on the proposed rule regarding payments for Primary Care Physicians ("PCPs") and charges for vaccine administration under the Vaccines for Children Program.

We are extremely supportive of the ACA's increased investment in primary care and we thank CMS for proposing regulations to fully implement this policy. We would like to underscore, however, that CMS must work to ensure that this investment produces maximum effect and that programmatic Medicaid dollars are well spent. In addition to the specific regulatory comments which follow below, we would like to make a few broad recommendations for ensuring CMS optimizes this investment in primary care:

- CMS should develop metrics to assess whether these dollars have served the ultimate goal – increasing access to primary care for Medicaid recipients. CMS will need to develop some baseline measure of access (pre-2013) and then have some way to measure the impact of increased reimbursement on access (in

Calendar Years (CY) 2013 and 2014, and beyond). This will require more than just reviewing numbers of participating providers, which can often be misleading, as providers may serve a minimal number of Medicaid patients and/or not accept new Medicaid patients. The measures should include nuanced data points such as waiting times, travel times/distances to providers, and provider panel sizes. We realize access will be a difficult metric to develop, particularly in light of the dramatic changes to insurance status in 2014. However, we believe a demonstrable increase in access will be essential to justify a continuation of the increased funding for PCPs after CY 2014 and possibly increased funding for other services. (While primary care is clearly a threshold concern, we note that Medicaid enrollees often have similar difficulty accessing specialist services.) Providers, who have long argued that payment rates are the reason for low participation rates, should also have a responsibility in helping CMS document the benefits of the investment.[1]

- The majority of Medicaid enrollees are in managed care plans, and that proportion is climbing. CMS must actively monitor managed care entities to ensure that increased primary care funding is sought and ultimately distributed to providers. Managed care entities may have an incentive to keep the extra funding (or simply avoid the administrative efforts to pursue it). If providers perceive that managed care organizations have kept the money, it may cause serious damage to Medicaid participation.
- We understand that in developing this regulation CMS was limited by narrow statutory language. Nonetheless, we encourage CMS to continue to think broadly about the purpose of this primary care funding in the broader context of the ACA. We are concerned that inflexible restrictions by provider type and service type will only serve to reinforce health care "silo-ing" and undercut the broader ACA intent to better integrate care. We believe the ACA's consistent focus on primary care and integrated care argues for a broad regulation.

§ 438.6 Contract requirements.

NHeLP commends CMS for requiring in § 438.6(c)(5) that managed care entities fully implement the primary care provider payment increase across all types of managed care relationships. We recognize that implementing this provision in a managed care or capitated system presents challenges. While we believe CMS has developed a reasonable methodology for identifying eligible providers and services in the general managed care context, we are concerned about how this policy will be implemented in the specific case of managed care entities that pay their providers based on capitated

[1] For example, the California Medical Association (CMA) has been the plaintiff in numerous recent lawsuits challenging unsupported payment reductions to the already extremely low reimbursement rates for physician services under the Medi-Cal program. CMS should confer with CMA, and other similar physician groups that have challenged payment reductions, for assistance in developing appropriate statistical measures for access.

rates. While a State's capitation payment to such a managed care entity is based on actuarial analysis which estimates primary care spending, the managed care entity typically negotiates a capitated payment to its providers. We do not understand how CMS would identify and compare these capitated services with Medicare payments.

Because more than two-thirds of Medicaid enrollees are enrolled in managed care plans, we encourage CMS to maintain strong rules to ensure that increased payments made to those plans are truly passed on to providers. While we understand that fully addressing these concerns may present some additional administrative burden to managed care entities, we urge CMS to maintain its proposed regulatory approach which is balanced and, as CMS notes, otherwise does not "require that managed care plans modify the terms of their payments to eligible primary care physicians beyond the increase in payments for primary care services required by the statute." 77 Fed. Reg. 27679.

NHeLP most strongly commends the approach identified by CMS in the preamble to the regulation for monitoring managed care implementation of the provider payment increases, including "[s]tate-by-state review of managed care contracts and applicable procedures" by CMS, the reporting of "all information needed to document expenditures" by managed care entities to states and by states to CMS, and the reporting of "data on primary care services" from managed care entities to states. 77 Fed. Reg. 27678. NHeLP believes this requirement for managed care entities to share contracts and information with CMS is an absolutely necessary prerequisite to implementing the provider payment policy in the managed care context.

We are concerned, however, that the regulation itself does not reflect the excellent approach set out in the preamble. If anything, the language of § 438.6(c)(5)(vi)(B) may diminish CMS' authority to access the documentation needed to monitor implementation by requiring managed care entities to provide "sufficient documentation … as determined *by the State*." (Emphasis added). The regulation fails to codify the requirement for states to share with CMS contracts, applicable procedures, and all information needed to document expenditures, as described in the preamble. We also recommend that CMS include timelines for the sharing and review of contracts to ensure that the processes happen quickly given the short two-year time window. MCOs should be required to provide the relevant contracts to the state Medicaid agency by November 1, 2012, so that the agency has sufficient time to review and approve the payment arrangements prior to January 1, 2013. After the initial review, CMS should require MCOs to provide copies or new or revised contracts within 15 days of entering into such contracts, so that the state agency can conduct ongoing compliance reviews. CMS should also require auditing, with results reported to CMS, after the close of each year to assure compliance. Finally, CMS should require MCOs to refund any supplemental payments that it failed to properly pass through to the PCPs.

RECOMMENDED LANGUAGE: Add to § 438.6 new section (n):

(n) For all MCO, PIHP, and PAHP contracts a state Medicaid agency enters, the state Medicaid agency must:
(1) Within 15 days of entering into a new or revised contract, provide to CMS copies of the contracts ;
(2) Require the MCO, PIHP, or PAHP contractor to report all information needed to document expenditures on primary care services and data related to primary care services; and
(3) Provide to CMS all information in subparagraph (2) on at least a quarterly basis.

§ 438.804 Primary care provider payment increases.

We commend CMS' framework for regulating state methodologies for increasing primary care payment in the managed care context. Specifically, we support the requirement at § 438.804(a)(3) that CMS must approve the methodology and that the submission must be made *prior* to CY 2013. We believe it was CMS's intent to require both submission *and approval* prior to CY 2013, and recommend CMS edit the regulation for clarity on this point.

NHeLP believes the four step methodology described in the preamble is a reasonable way to apply the provision to managed care, particularly given CMS' consultation with states in the development of the proposed regulation. We note, however, that the regulation at § 438.804 conditions increased federal financial participation ("FFP") for states on making "estimates" and developing data instead of conditioning FFP on using the estimates and data.

RECOMMENDED LANGUAGE: Amend § 438.804 as follows:

(a) * * *
(1) The State makes***, and bases rates on,*** a reasonable estimate of the increased amounts paid for specified primary care services provided by eligible primary care physicians resulting from the contractual requirement under § 438.6(c)(5)(vi), based on information received from the managed care provider for services furnished as of July 1, 2009.
(2) The State develops***, and implements rates using,*** a methodology for identifying the differential in payment between the provider payments that would have been made by the managed care provider on July 1, 2009 and the amount needed to comply with the contractual requirement under § 438.6(c)(5)(vi).
(3) The State must submit the methodology in paragraph (a)(2) of this section to CMS for approval ***and obtain such approval*** before the beginning of CY 2013.

§ 441.515 Administration fee requirements.

NHeLP supports the provision at § 441.515(a)(2) prohibiting a provider from denying administration of a vaccine due to the inability of the child's parents or legal guardian to pay an administration fee.

§ 447.400 Primary care services furnished by physicians with a specified specialty or subspecialty.

NHeLP strongly commends the inclusion of primary care subspecialties in the payment increase policy. This is particularly important in areas, such as pediatric primary care, where serious access problems exist regarding specialized primary care beyond basic preventive visits. Specifically, we support CMS' policy of relying on Board approval *and* supplementing those criteria with the "60% of coding" threshold. We believe the 60% of coding threshold, or some similar standard, is critical to include a wide range of providers who may provide applicable services irrespective of their Board certification status. Additionally, the 60% threshold is also important to ensuring enhanced matching funds reach diverse providers and communities, since providers of color have disproportionately low Board certification rates. In addition:

- We urge CMS to be expansive in consideration of qualifying Boards, because in many cases strict Board criteria might be too arbitrary. For example, many primary care providers may have the option of pursuing one of several possible Board certifications for their specialty; such a provider should not be paid less for the same service because they were certified by one board instead of the other. Such a policy would have the additional advantage of reducing the number of providers the Medicaid agency would need to review for the 60% threshold.
- We recommend CMS clarify whether the 60% threshold applies to codes billed (for example, "codes 001, 017, and 088") or the services billed (for example, "code 001 billed 2 times, code 017 billed 1 time, and code 088 billed 7 times"). In the examples, if only code 088 was an applicable primary care code, then in the first example the provider would bill only 33% PCP codes (1 of the 3 codes billed) but in the second example the provider would have billed 70% PCP codes (7 of the 10 services billed). We believe it was CMS' intent to implement the second policy, with which we agree, and we recommend CMS clarify its intent.

NHeLP commends the provision at § 447.400(a) allowing enhanced payment for services provided by non-physician practitioners under the supervision of a physician. To maintain sufficient access to primary care services, particularly in years with millions of new enrollees, it is essential to reward services provided by a wide range of providers, such as nurse practitioners and physician assistants.

While NHeLP recognizes that there are statutory limits on the types of primary care providers included for the purposes of the payment increases, NHeLP believes the

intent of the statute was to increase reimbursement for providers who are providing important primary care services. As such, NHeLP believes it is a mistake for the regulation to exclude obstetricians and gynecologists ("OB/GYN") from the list of eligible providers. OB/GYNs are among the highest volume providers of preventive services for women. Furthermore, OB/GYNs play a critical systemic role as the entry point into the health system for women and are the only providers many women visit on a regular basis. Considering that OB/GYN providers are the only primary care providers for a significant population of women, failure to include OB/GYNs in this regulation will clearly have a discriminatory impact on primary care for women. NHeLP believes this outcome stands in stark contrast to the intent of the primary care provision and the ACA more broadly.

§ 447.405 Amount of required minimum payments.

NHeLP strongly commends the inclusion of unique Medicaid services which Medicare does not reimburse. It is crucial to promote the coverage of these Medicare gaps which may arise because of Medicare's broad focus on services used by older adults and persons with disabilities. There are important primary care services for children, for example, which are not reimbursed by Medicare. We also note that there appear to be some words missing in proposed § 447.405(a)(1) so CMS should correct the text.

We understand the concerns involved with multiple updates to payment rates during the year based on Medicare physician fee schedule ("MPFS") updates. However, given that this payment increase is only in effect for two calendar years, yearly adjustments would mean there is only one adjustment over the course of the entire duration. We recommend that CMS require states to adjust the rates every six months – but not every time MPFS rates change. CMS should also set some timeliness standard for the implementation of the rate changes.

NHeLP generally commends CMS' effort to raise the administration fees for vaccinations. Raising reimbursement for vaccine administration promotes a low-cost high-impact public health service of critical importance.

However, despite the advances made in CMS' regulation, we believe the regulation does not go far enough. To begin with, we do not agree with CMS' broad conclusion that the "Vaccines for Children (VFC) program requirements do not permit payment for each vaccine/toxoid component administered." (77 Fed. Reg. 27678.) The statutory requirements of Social Security Act § 1928 simply require that payment not exceed actual cost. Furthermore, if anything, the intent of the VFC program *supports* component-based payment.

More importantly, the statutory requirement of the ACA is to raise primary care service payment to Medicare levels, and primary care services are defined at Social Security Act § 1902(jj) (created by ACA Reconciliation § 1202(a)(1)(B)) to include services

related to immunization administration. On its face, § 1902(jj)(2) identifies codes as "subsequently modified." The code list in § 1902(jj) was enacted in 2010 (in the ACA), and the code modifications for component-based immunizations enacted in 2011. Therefore, while it does raise rates, the regulation falls short of the statutory standard to the extent it allows states to pay less than is required by the 2011 component-based code methodology currently used by Medicare.

We recommend CMS change the regulation to meet this statutory requirement and also as a matter of policy. The current reimbursement methodology creates a disincentive for providers to comply with optimal medical practice: more multi-component vaccinations and less "sticks" and visits. The applicable Medicare standards, which offer a primary vaccination code (90460) which is billed once *and* a modifier code (90461) which can be billed multiple times for multi-component vaccinations, creates proper incentives for providers to follow best clinical practice, promotes uniformity in payment, and most importantly, will maximize the number of children actually receiving vaccinations.

§ 447.415 Availability of Federal financial participation (FFP)

NHeLP commends the clarification that enhanced FFP will be available for services provided to dual eligibles. This policy will help expand access to services for dual eligibles, because providers will be assured a Medicaid payment to complete the Medicare rate.

Conclusion

In conclusion, we would like to thank CMS for taking important steps towards improving access to primary care services in these regulations. We urge CMS to consider our recommendations to ensure that vulnerable beneficiaries truly benefit from this provision and that programmatic dollars are well spent. If you have questions about these comments, please contact Leonardo Cuello at (202) 289-7661 or cuello@healthlaw.org. Thank you for consideration of our comments.

Sincerely,

Emily Spitzer,
Executive Director