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June 12, 2012

Cindy Ruff
Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations
Family and Children's Health Programs Group
7500 Security Boulevard, S2-01-16
Baltimore, MD 21244

Dear Ms. Ruff:

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 litigation and technical support to poverty and disability rights advocates, health care providers and individuals.

We are writing in response to a CMCS Informational Bulletin (March 30, 2012) outlining new proposed policies for screening children enrolled in Medicaid for elevated blood lead levels (EBLs). NHeLP supports CMS' goal to improve screening of children at risk for lead exposure. However, NHeLP has serious concerns with CMS' proposal to end universal screening by testing the blood lead levels (BLLs) of children enrolled in Medicaid.

Given the serious health consequences for children with even low levels of blood lead poisoning (<10 ug/dL) and the states' dismal screening track records to date, NHeLP urges CMS to require states to improve compliance with the universal screening and testing standard as the required first step for a state to move to a targeted screening approach. NHeLP further urges CMS to update the State Medicaid Manual to expressly provide for treatment and follow up for children with blood lead poisoning at levels below the current 10 µg/dL action level.

For over 20 years, federal law has required state Medicaid programs to cover "lead blood level assessment appropriate for age and risk factors" as part of EPSDT services for children and youth under age 21.¹ Federal policy requires that all Medicaid-eligible children receive a blood lead test at 12 and 24 months of age to screen for elevated blood levels of > 10 µg/dL. Children between the ages of 36 and 72 months of age must

¹ 42 U.S.C. §1396d(r)(1)(B)(iv).

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receive a screening test if they have not previously received one. EPSDT also requires states to provide case management and treatment services, as appropriate depending on the lead levels detected as a result of the test.²

CMS adopted these universal screening requirements as part of a 1993 settlement of a nationwide class action lawsuit charging the federal government with failing to implement the Medicaid Act's requirement for appropriate lead testing. The case, *Thompson v. Raiford*, was co-counseled by NHeLP, the Natural Resources Defense Council, NAACP Legal Defense Fund, and the ACLU of Southern California.

However, CMS and state Medicaid agencies have done a poor job implementing the screening requirement. For example, in 2001, CMS reported that 12% of children enrolled in Medicaid were tested for lead poisoning.³ In 2010, the most recent year for which data are available, this percentage had actually *decreased* and only 8.5% of children were reported as tested.⁴ Although national surveys show an overall reduction in EBLs, CMS' own data show that most children in Medicaid go untested and presumably untreated for blood lead poisoning.⁵

CMS now proposes to replace universal screening through blood testing with a "targeted" approach that allows states greater flexibility in screening children for elevated blood levels. This targeted approach permits a variety of other methods to determine if a child is at-risk and should be tested for lead poisoning, including use of census data, ZIP code and Geographical Information Systems (GIS) mapping, and verbal risk assessments conducted by clinicians or others.⁶ NHeLP's concerns with this approach are discussed below.

1. CMS should work to improve blood lead testing which is the most effective and efficient screening tool

The National Committee for Quality Assurance emphasized in a 2011 report that blood lead testing "is an inexpensive way to detect the presence of lead in a child's

² CMS, STATE MEDICAID MANUAL § 5123.2.

³ CMS, ANNUAL EPSDT PARTICIPATION REPORT FY 2001, CMS FORM 416, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-Periodic-Screening-Diagnosis-and-Treatment.html>.

⁴ CMS, ANNUAL EPSDT PARTICIPATION REPORT FY 2010, CMS FORM 416, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Downloads/2010-National-Data.pdf>.

⁵ Robert L. Jones, et al., *Trends in Blood Lead Levels and Blood Lead Testing Among US Children Aged 1 to Years, 1988-2004*, PEDIATRICS, March 2009, at e376.

⁶ CDC, U.S. DEPT. OF HEALTH AND HUMAN SERV., RECOMMENDATIONS FOR BLOOD LEAD SCREENING OF MEDICAID-ELIGIBLE CHILDREN AGED 1-5 YEARS: AN UPDATED APPROACH TO TARGETING A GROUP AT HIGH RISK, MMWR, Aug. 7, 2009, 1-11.

environment and reduce further exposure.”⁷ Researchers have repeatedly concluded that blood lead testing is more effective than other risk assessment tools in identifying children with lead poisoning, particularly at levels below 10 µg/dL. A January 2012 study published in *Public Health Nursing* examined whether screening tools used to identify children at risk for EBLs (>10 µg/dL), such as mapping and verbal assessment, are sufficiently sensitive to identify children with lower levels of blood lead poisoning.⁸ Researchers found that verbal assessment “failed to identify children with measurable BLL 84% of the time.”⁹ In the *Public Health Nursing* study, Brenda Dyal and her colleagues concluded:

Failure of the verbal lead risk assessment tool to accurately identify the children in this study with measurable BLL demonstrates its ineffectiveness as a screening tool and *supports the need for public policy requiring universal capillary fingerstick lead screening by laboratory analysis for all children in order to prevent the potential long-term consequences of low-level lead contamination.*¹⁰

NHeLP also has concerns with sole reliance upon ZIP codes and mapping. The Dyal study also noted that using ZIP codes and geographic mapping systems “should not be relied upon to determine who should receive capillary BLL testing” because at-risk populations are often transient; in addition, exposure is increasingly due to toys and other imported objects.¹¹

Because the hazards of lead poisoning in children are so severe, and the benefits of early detection and treatment are so significant, child advocates, and researchers have developed and promoted strategies and recommendations to improve universal lead screening compliance rates. These include better education and monitoring of providers, financial rewards and penalties, and ensuring that reimbursement and capitation rates are adequate for blood lead testing and follow up.¹²

⁷ NATIONAL COMMITTEE ON QUALITY, CONTINUOUS IMPROVEMENT AND THE EXPANSION OF QUALITY MEASUREMENT, THE STATE OF HEALTH CARE QUALITY 2011, at 76, available at <http://www.ncqa.org/LinkClick.aspx?fileticket=J8kEuhuPqkx%3d&tabid=836>.

⁸ Brenda Dyal, D.N.P., F.N.P.-B.C., *Are Lead Risk Questionnaires Adequate Predictors of Blood Lead Levels in Children?*, PUB. HEALTH NURSING, January/February 2012, at 7,8.

⁹ Id.

¹⁰ Id. at 7 (emphasis added).

¹¹ Id.

¹² DONNA KEYSER, ET AL., RAND CORP., IMPROVING CHILDHOOD BLOOD LEAD LEVEL SCREENING, REPORTING, AND SURVEILLANCE IN ALLEGHENY COUNTY, PENNSYLVANIA, 2006, available at http://www.rand.org/content/dam/rand/pubs/monographs/2006/RAND_MG423.pdf; CDC, RECOMMENDATIONS FOR BLOOD LEAD SCREENING OF YOUNG CHILDREN ENROLLED IN MEDICAID: TARGETING A GROUP AT HIGH RISK, MMWR, Dec. 8, 2000 49, 8-12; Anne M. Wengrovitz and Manjusha P. Kulkarni,

Yet, the implementation of these strategies has been, at best, sporadic and unsustainable. This lack of progress has frustrated many health advocates and policymakers, including the Centers for Disease Control and Prevention's (CDC) Advisory Committee for Childhood Lead Poisoning Prevention (ACCLPP). In a 2009 report, ACCLPP recommended allowing some states to end universal blood lead screening and speculated that targeted screening might increase screening rates.¹³ Nevertheless, the ACCLPP recognized that many of the same implementation strategies needed to improve universal, mandatory screening, including better education and monitoring of providers, and adequate reimbursement, would be needed to implement targeted, optional screening.¹⁴

Indeed, if targeted screening is to be undertaken with serious purpose, it will require state Medicaid agencies and public health officials to devote *additional* resources to developing tracking and mapping tools and training staff and providers, all to identify children who may be at risk and should be subsequently tested for lead poisoning.

2. CMS should establish a clear standard, based upon reliable data, to determine when a state may switch from universal to targeted screening

To implement the new targeted screening policy, CMS must also establish parameters governing when a state will be permitted to switch from universal to targeted screening. The CDC's 2009 recommendation for targeted screening in Medicaid offers little guidance. It proposes states utilize data provided by the CDC-funded childhood lead poisoning program to assess local lead exposure risks so that state Medicaid programs can target screenings as part of a state's overall lead screening plan.¹⁵ A growing number of states without federally funded programs (now 16) will be required to continue universal screening until they develop a data-driven risk assessment plan.¹⁶ However, the CDC recommendation sets no threshold or standard on the type, amount or quality of data; nor does it suggest a process for accessing the adequacy of a state's lead plan.

The CDC lead prevention program is facing severe budget cuts in the FY 12 and FY 13 budgets.¹⁷ This defunding will pose a significant obstacle to implementing Medicaid

Strategies to Improve Medicaid Screening and Treatment for Lead Poisoning, CLEARINGHOUSE REV. J. POV. & RIGHTS, at 26-36, May-June 2005.

¹³ CDC, RECOMMENDATIONS FOR BLOOD LEAD SCREENING OF YOUNG CHILDREN ENROLLED IN MEDICAID: TARGETING A GROUP AT HIGH RISK, MMWR, Aug. 7, 2009, at 9.

¹⁴ *Id.* at 10.

¹⁵ *Id.* at 6.

¹⁶ *Id.* at 8.

¹⁷ See National Center for Healthy Homes, at <http://www.nchh.org/Policy/National-Policy/Federal-Appropriations.aspx>.

targeted screening that relies so heavily on the CDC programs and data. It also places an added burden on states, which will need to fund their own lead surveillance and risk assessment in the absence of federal funds. Given the current serious budget pressures, it is difficult to imagine that states will increase funding for lead surveillance and planning, even if it presents the opportunity to opt out of universal screening for Medicaid. However, CMS should not permit states to end universal screening based upon insufficient, poor quality, or outdated data.

NHeLP urges CMS to establish a clear standard to determine when a state may switch from universal to targeted screening. We recommend a standard of 80% or more compliance with lead poisoning screening and reporting based on state reports using CMS 416 Form, which is consistent with the overall EPSDT participation goals established by CMS, State Medicaid Manual, § 5360. In fact, an 80% threshold may actually increase compliance rates, especially from states eager to end universal screening. From this, it is clear that, at this time, NHeLP does not support using the current HEDIS lead screening measure to replace CMS 416 reporting. HEDIS does not reflect the Medicaid requirement that young children be screened at 12 and 24 months. And while we understand that states complain about the accuracy of Form 416 reports, these complaints should not result in removal of the lead screening cell. We note that Medicaid-contracting managed care plans are able to collect and report accurate data (for example, in external quality review reports), so accurate lead reporting on the Form 416 should be enforced.

There may be other approaches and other standards, such as statistical sampling, or using NHANES or HEDIS surveys. However, CMS 416 data consists of hard numbers and a more reliable reporting system. Unlike the CDC lead poisoning program, Medicaid screening, data collection, and assessment is not as vulnerable to the uncertainties of the federal appropriations process.

3. CMS should update the State Medicaid Manual consistent with the CDC's determination that there is no safe level for blood lead in children

Under the current CMS State Medicaid Manual, a BLL of > 10 µg/dL triggers a requirement for patient management and treatment, including follow up blood tests and an investigation to determine the source of lead.¹⁸ However, seven years ago, the CDC concluded that there is no “safe” level for blood lead in children after reviewing

¹⁸ CMS, STATE MEDICAID MANUAL § 5123.2.

overwhelming evidence that BLLs below the 10 µg/dL “level of concern” can cause serious mental and physical impairment in children.¹⁹

The CMCS Informational Bulletin states that CMS has historically followed CDC recommendations for lead screening. The CDC recently adopted a recommendation from the ACCLPP which replaces the 10 µg/dL “level of concern” with a new reference value based upon the 97.5th percentile of the BLL distribution of children 1-5 years old in the United States.²⁰ The 97.5th percentile is currently calculated at 5 µg/dL and will be updated every 4 years.²¹ NHeLP urges CMS to incorporate this new CDC reference value as it develops lead screening policies for state Medicaid programs. This change would support health professionals in the follow up and treatment of children with blood lead poisoning < 10 µg/dL. However, we note that it would fail to address lower levels of blood lead poisoning levels < 5 µg/dL. Numerous studies show that even BLLs at 2 µg/dL have measurable impacts on children, including lower IQ, long term behavioral health problems, and diminished school performance.²²

By incorporating the CDC’s revised blood lead standard, CMS can have a tremendous impact by providing for follow up and treatment of children suffering from the effects of blood lead poisoning. By detecting and treating blood lead poisoning in children early on, the Medicaid program and society at-large reaps significant benefits. One recent study found that for every dollar spent to reduce lead hazards, “\$17-\$220 would be returned in health benefits including increased IQ, lifetime earnings, tax revenue, reduced spending on special education, and reduced criminal activity.”²³

In sum, we urge CMS to take the following steps:

1. Work with state Medicaid agencies, providers, advocates and other stakeholders to improve blood lead testing compliance rates.
2. CMS should establish a clear standard, based upon reliable data, to determine when a state may switch from universal to targeted screening.

¹⁹ CDC, PREVENTING LEAD POISONING IN YOUNG CHILDREN, Aug. 2005, at 1, available at <http://www.cdc.gov/nceh/lead/publications/PrevLeadPoisoning.pdf>.

²⁰ CDC, RESPONSE TO ADVISORY COMMITTEE ON CHILDHOOD LEAD POISONING PREVENTION RECOMMENDATIONS IN ‘LOW LEVEL LEAD EXPOSURE HARMS CHILDREN: A RENEWED CALL OF PRIMARY PREVENTION,’ available at http://www.nchh.org/Portals/0/Contents/CDC_Response_Lead_Exposure_Recs.pdf.

²¹ Id. at 6.

²² See Alder, T, *Questioning lead standards: Even low level shave points off IQ*, ENVTL. HEALTH PERSP., 113(7), 473-474 (2005); B.P. Lanphear, et al., *Low-level environmental lead exposure and children’s intellectual function: An international pooled analysis*, ENVIRONMENTAL HEALTH PERSPECTIVE, 113, 894-899 (2005); H.L. Needleman & P.J. Landrigan, *What level of lead in blood is toxic for a child?* Letter. AM. J. OF PUB. HEALTH, 94(1),8 (2004).

²³ Gould, E, *Childhood Lead Poisoning: Conservative Estimates of the Social and Economic Benefits of Lead Hazard Control*, ENVTL. HEALTH PERSP., 117, 1162-1167, at 1166.

3. CMS should update the State Medicaid Manual consistent with the CDC's determination that there is no safe level for blood lead in children.

If you have any additional questions, please feel free to contact NHeLP staff attorney Wayne Turner at (202) 289-7661 or at turner@healthlaw.org.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Emily Spitzer". The signature is fluid and cursive, with the first name "Emily" written in a larger, more prominent script than the last name "Spitzer".

Emily Spitzer,
Executive Director