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December 4, 2020

The Honorable Alex M. Azar, Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Subject: Comments on the Securing Updated and Necessary Statutory Evaluations Timely Rule
Re: RIN 0991–AC24 Securing Updated and Necessary Statutory Evaluations Timely

Dear Secretary Azar:

First Focus on Children is a bipartisan advocacy organization dedicated to making children and families a priority in federal and budget decisions. We advocate on behalf of children in all areas of their lives, inclusive of several programs within the Department of Health and Human Services (HHS).

We appreciate the opportunity to provide comments on the proposed rule, "Securing Updated and Necessary Statutory Evaluations Timely" (hereinafter referred to as the "Regulations Rule"). The proposed rule would retroactively impose an expiration provision on most HHS regulations and establish "assessment" and "review" procedures to determine which, if any, regulations should be retained or revised. The Regulations Rule is an impractical proposal that would create tremendous administrative burden for HHS and would wreak havoc across a broad swath of Department programs and regulated entities from Medicaid and Medicare to Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). We also strongly object to the truncated 30-day comment period which is insufficient for a rule of this broad scope with potentially harmful effects. We urge HHS to immediately withdraw this proposed rule.

The proposed rule would create tremendous administrative burden for HHS

HHS asserts that the Regulations Rule will promote "accountability, administrative simplification [and] transparency. . . ."[1] In fact, the proposed rule would create a significant administrative burden that would divert resources from critical work, including efforts to address the COVID-19 pandemic. HHS itself estimates that the proposed rule would cost nearly $26 million dollars over 10 years, needing 90 full-time staff positions to undertake the required reviews.[2] Within the first two years, HHS estimates the need to assess at least *12,400* regulations that are over 10 years old.[3] However, these estimates likely underestimate the time and money involved in the review process, and do not accurately account for complications that may arise.

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[1] 85 Fed. Reg. 70104.
[2] 85 Fed. Reg. 70116.
[3] 85 Fed. Reg. 70112. To be specific, HHS states that "because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480." *Id.*

That is an incredible amount of regulations to review and the time and people-power involved are incongruous with running an agency that is there to help people.

The Regulations Rule would adversely affect HHS's ability to focus on the administration of current programs, to issue new regulations, and appropriately review current regulations that need modification. In addition, several regulations implementing important parts of the Affordable Care Act are approaching their ten-year anniversary, like the Medicaid cost-sharing rule. Regulations like these would need to be reviewed within the next two years, or they would expire. However, the underlying law still exists, even if the regulations expire. Without the cost-sharing rule, states would not have clear guidance on how to implement cost-sharing amounts. Havoc would be created across the country for something as critically needed as health coverage.

Especially during crisis situations like COVID-19, it is critically important that HHS have the flexibility and bandwidth to shift focus and respond quickly to immediate needs. Children and their families are affected by many regulations based in HHS, including childcare, immunizations, tobacco, financial aid to families, and through refugee programs. There are literally a multitude of ways this rule could harm children.

The current rule would wreak havoc across all HHS programs

Regulations play an important role in implementing HHS policies and programs including safety net programs such as Medicaid and the Children's Health Insurance Program (CHIP), which provide health coverage for over 75.5 million people, including 36.6 million children. A strong regulatory framework provides states the clarity they need to run these programs on a day-to-day basis, gives providers and managed care plans guidance as to their obligations, and explains to beneficiaries what their entitlement means. The Regulations Rule would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process.

The bigger danger posed by the Regulations Rule is that important regulations may be arbitrarily rescinded because there are simply not enough HHS staff or resources to undertake such a sweeping review process. Regulations that do not complete the complicated and time consumer review process would summarily expire, potentially leaving vast, gaping holes in the regulatory framework implementing HHS programs and policies.

For example, multiple insurance affordability programs including Medicaid and CHIP rely on regulations at 42 C.F.R. § 435.603 to determine financial eligibility using Modified Adjusted Gross Income (MAGI) methodologies. If this regulation were to simply disappear, programs would be free to redefine MAGI household and income counting rules, with no standards, consistency, or accountability. Arbitrarily rescinding large swaths of regulations would wreak havoc in HHS programs, leading to untold harm to the millions of people who rely on those programs. Additionally, Medicaid for children in known as the Early Periodic Screening Diagnosis and Testing program (ESPDT) that provides child specific medical care and is considered the gold standard in coverage for children. The specific regulations within ESPDT include:

42 CFR § 441.55 State plan requirements.

42 CFR § 441.56 Required activities.

42 CFR § 441.57 Discretionary services.

42 CFR § 441.58 Periodicity schedule.

42 CFR § 441.59 Treatment of requests for EPSDT screening services.

42 CFR § 441.60 Continuing care.

42 CFR § 441.61 Utilization of providers and coordination with related programs.

42 CFR § 441.62 Transportation and scheduling assistance.

This structure of regulations guides state Medicaid officers and medical providers the outline needed to manage a program that serves almost 40 million children a year. Advising states on what is required in EPSDT, including the medical providers who are allowed to serve children and precisely what the services are that children need at each medical appointment during their well-child exams, known as the Periodicity Schedule, all falls within these regulations. Undoing or losing track of any of these regulations because of this rule would mean the well-designed scaffolding of children's coverage including provider networks, covered benefits, and reimbursement structures, could begin to fall apart. That is a risk we cannot take concerning our nation's children.

Along with health coverage, we are deeply alarmed about other HHS regulations that impact children, including, the Temporary Assistance for Needy Families (TANF) program. TANF is the only federal program that provides cash assistance to families with very low incomes, with children making up the vast majority of TANF recipients. Cash assistance allows parents to provide resources that supports children's healthy development and future success and provides them with the flexibility to meet their family's unique needs.

Despite the importance of TANF for child well-being, it is in desperate need of reform. Just 22 percent of all poor families that are eligible for TANF cash assistance receive it, and due to its nature as a fixed block grant, TANF is not able to effectively respond during times of increased need. In addition, states overwhelmingly use TANF funds for other important priorities other than its original intent of reducing child poverty and getting families back to work.

Implementing this rule would take precious time away from HHS's ability to focus on making much-needed improvements to TANF so it can more effectively reduce child poverty and improve child well-being.

The FDA regulations regarding tobacco access and use among children and youth are of great concern as well. E-cigarettes and vaping are among the most dangerous threats facing children today. The use of e-cigarettes by youth has escalated rapidly in recent years, fueled by youth attraction to flavored products, placing a new generation at risk of nicotine addiction and tobacco use. E-cigarette use among youth has reached epidemic proportions, with about one in five American kids now using these highly-addictive products.[4] It is essential that the FDA be allowed to focus on its critical task of protecting children from addictive and deadly tobacco products, and not on unnecessary and burdensome regulation. FDA has issued several advanced notices of proposed rulemaking on important issues, including a product standard on nicotine in combusted cigarettes and the regulation of flavors in tobacco products. The public health of the nation, particularly its youth, would be far better served by the FDA dedicating its finite resources to make progress on those initiatives, rather than on the proposed rule.

Another HHS office in which many regulations address children is the Office of Refugee Resettlement (ORR). This office is responsible for the care and custody of unaccompanied immigrant children—children who arrive the United States without legal status and without a parent or legal guardian available to care for them. ORR also runs the unaccompanied refugee minors program for children who have been granted legal

[4] CDC, *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 Morbidity & Mortality Wkly. Rep. Surveillance Summaries (Sept. 9, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf

protection. Under federal law, children in ORR custody must be placed in the least restrictive setting and be provided with specific services prior to their safe and prompt release to family or another sponsor.[5]

Despite ORR's important role, the agency has repeatedly deviated from its child welfare mandate. ORR has coordinated with immigration enforcement agencies, prolonging the length of time children spend in its custody and away from family.[6] The agency has increasingly placed children in inappropriate large-scale institutionalized settings, including secure and unlicensed settings, instead of small family- and community-based placements.[7] After the child separation policy that resulted in over 5,000 children being separated from their parents, the HHS Office of the Inspector General found that many service providers struggled to address the mental health needs of children in their care.[8]

Given these many challenges, ORR staff should dedicate their time to developing and implementing policies are in the best interests of unaccompanied children. Implementing this rule would take focus away from these much-needed changes and compromise unaccompanied children's safety and well-being.

The implementation of this rule would also impair the work of the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA leads public health efforts to advance the behavioral health of the nation and reduce the impact of substance use and mental illness on Americans. SAMHSA has promulgated important rules including those governing the use of Medication Assisted Treatment and Opioid Treatment Programs, as well as the health information privacy rule of 42 CFR Part 2. These regulations are helping to combat the opioid epidemic and we cannot afford to put them at risk. Compared to other agencies within HHS, SAMHSA is small and cannot afford to be overloaded with unnecessary regulatory work. First Focus on Children is committed to lessening the negative impacts of the opioid epidemic on children, especially now as overdose deaths and substance use are increasing during the COVID-19 pandemic. Instead of dealing with administratively burdensome work, SAMHSA staff should be focused on implementing The SUPPORT for Patients and Communities Act which became law in 2018**,** getting important grant dollars to behavioral health programs, and supporting mental health services which are in great demand during this difficult time.

The administration of federal child care funding by the Administration for Children and Families (ACF) would also be negatively impacted by this rule. In 2016 HHS revised the regulations governing the Child Care and Development Fund (CCDF) to implement the changes made by the 2014 Child Care and Development Block Grant reauthorization. The rulemaking process took nearly two years and incorporated input from a wide variety of stakeholders including state officials and members of Congress. The regulation governs important pieces of the reauthorization that were passed on a bipartisan basis: protecting the health and safety of children in child care including through enhanced and increased criminal background checks for staff; helping parents make informed consumer choices and access information to support child development; providing equal access to stable, high-quality child care for low-income children; and enhancing the quality of child care and the early childhood workforce. States need these regulations in order to meet the goals of the

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[5] 8 U.S.C. sec. 1232(c)(2)(A). Flores Settlement Agreement, Flores v. Reno, No. cv 85-4544-RJK (Px) (C.D. Cal. Jan. 17, 1990).

[6] *The ORR and DHS Information-Sharing Agreement and its Consequences*, Justice for Immigrants, October 2019, https://justiceforimmigrants.org/wp-content/uploads/2019/10/Updated-formated-MOA-backgrounder-10.2.19.pdf.

[7] Neha Desai, Melissa Adamson, and Lewis Cohen, *Child Welfare and Unaccompanied Children in Federal Immigration Custody: Data and Research Based Guide for Federal Policy Makers*, National Center for Youth Law, December 2019, https://youthlaw.org/wp-content/uploads/2019/12/Briefing-Child-Welfare-Unaccompanied-Children-in-Federal-Immigration-Custody-A-Data-Research-Based-Guide-for-Federal-Policy-Makers.pdf

[8] *Care Provider Facilities Described Challenges Addressing Mental Health Needs of Children in HHS Custody*, U.S. Department of Health and Human Services Office of Inspector General, September 2019, https://oig.hhs.gov/oei/reports/oei-09-18-00431.pdf.

reauthorization and successfully implement the program that enables hundreds of thousands of children and their families to access care.

Additionally, CCDF regulations regarding state matching expenditures are more than 10 years old. These regulations added additional flexibility to state funding of child care, enabling states to more easily meet their matching requirements and ensure they are drawing down all available funds to serve families. Arbitrarily rescinding these regulations on CCDF will likely reduce the number of families served, which is especially harmful at a time when state budgets are stretched as they are during the COVID-19 pandemic.

The proposed rule is unnecessary and HHS does not have the authority to propose automatic expiration dates on almost all regulations.

The Regulations Rule claims that automatic expiration dates give HHS the incentive necessary to conduct regular assessments of existing regulations and comply with the Regulatory Flexibility Act (RFA). First, HHS agencies already commonly update regulations when needed. For example, in 2002 the Centers for Medicare & Medicaid Services (CMS) promulgated new regulations implementing statutory changes to Medicaid managed care.[9] In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.[10] CMS took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.[11] This administration undertook further rulemaking to revise Medicaid managed care regulations, to "relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care."[12] HHS' contention that it needs to "incentivize" regulation review by imposing a mandatory rescission is simply not supported by the facts.[13]

Further, the RFA requires each agency to publish "a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities."[14] However, nothing in this forty-year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations.

In fact, this proposal is contrary to the Administrative Procedure Act's (APA) requirements for rulemaking. In the APA, Congress established clear procedures and standards for agencies seeking to modify or rescind a

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[9] CMS, *Medicaid Program; Medicaid Managed Care: New Provisions,* RIN 0938–AK96, 67 Fed. Reg. 40989 – 41116 (June 14, 2002), https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms2104f.pdf.

[10] CMS, *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules*, RIN 0938–AS25, 80 Fed. Reg. 31098–31296 (June 1, 2015), https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered.

[11] CMS, *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Final Rule*, RIN 0938–AS25, 80 Fed. Reg. 27498–27901 (May 6, 2016), https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered.

[12] CMS, *Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care (Final Rule),* RIN 0938–AT40, 85 Fed. Reg. 72754–72844, 72754 (Nov. 13, 2020), https://www.govinfo.gov/content/pkg/FR-2020-11-13/pdf/2020-24758.pdf.

[13] 85 Fed. Reg. 70099, 70106.

[14] 5 U.S.C. 610(a) (In the case of the RFA, periodically is defined as 10 years, unless such review is not feasible, in which case the review can be extended another 5 years).

rule. The APA requires agencies to go through the same rulemaking process to revise or rescind a rule as they would for a new rule, with public notice and the opportunity to comment.[15]

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expired.[16] We do not dispute that federal agencies can later amend existing regulations. However, the Regulations Rule would modify thousands of separate, distinct rules across HHS in a single stroke, in violation of the APA. HHS' attempt to apply a blanket amendment to 18,000 regulations violates the APA's requirements that review of an existing rule take place on an individual basis, requiring specific fact-finding relevant to the individual rule that the agency wants to amend,

Conclusion

The Regulations Rule is simply an attempt to sabotage and destroy duly promulgated regulations, by retroactively imposing an arbitrary end date to duly promulgated regulations. This rule is unnecessary, will wreak havoc in current HHS programs, will ultimately hurt children and families, and will tie the hands of the incoming Administration by detracting from critical issues like the COVID-19 pandemic, to undertake this time-consuming process. We strongly oppose this rule, and urge HHS to withdraw it immediately. Thank you for the opportunity to submit this comment. If you have any questions, please contact me at 202-657-0605 or Brucel@firstfocus.org.

Sincerely,

Bruce Lesley
President

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[15] 5 U.S.C. § 551(5);*see also* Maeve P. Carey, Specialist in Government Organization and Management, *Can a New Administration Undo a Previous Administration's Regulations?*, Congressional Research Service (Nov. 21, 2016), https://fas.org/sgp/crs/misc/IN10611.pdf ("In short, once a rule has been finalized, a new administration would be required to undergo the rulemaking process to change or repeal all or part of the rule."); Office of Information and Regulatory Affairs, Office of Management and Budget, The Reg Map 5 (2020) (noting that "agencies seeking to modify or repeal a rule" must follow the same rulemaking process they would under the APA).

[16] 85 Fed. Reg. 70104, fn 85 & 86, citing to separate, specific rulemakings modifying interim final rules implementing mental health parity and foreign quarantine provisions, respectively.