

June 13, 2017

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Centers for Medicare and Medicaid Services Request for Information on CMS Flexibilities and Efficiencies

Dear Administrator Verma:

Nemours Children's Health System (Nemours) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on a Request for Information (RFI) on CMS Flexibilities and Efficiencies. Nemours is an internationally recognized and integrated children's health system that owns and operates the Nemours/Alfred I. duPont Hospital for Children in Wilmington, Delaware, and Nemours Children's Hospital in Orlando, along with major pediatric specialty clinics in Delaware, Florida, Pennsylvania and New Jersey. Established as The Nemours Foundation through the legacy and philanthropy of Alfred I. duPont, Nemours offers pediatric clinical care, research, education, advocacy and prevention programs in the communities we serve. The Nemours promise is to do whatever it takes to treat every child as we would our own. We care for more than 400,000 patients each year and are committed to making family-centered care the cornerstone of our health system.

Nemours commends CMS for its commitment to advancing health care delivery transformation by seeking input on potential flexibilities and efficiencies within existing programs and regulations. We see particular opportunity in the areas of payment system redesign and health information exchange. Below are recommendations for each of these categories.

I. Payment System Redesign

Innovation Center

As part of the Innovation Center's Health Care Innovation Award (HCIA) Round 1, Nemours was awarded \$3.7 million to work with community partners in Delaware to better integrate clinical care with community-based prevention for children with asthma, including Medicaid beneficiaries. The target population included children with asthma receiving care in a family-centered medical home at each of three Nemours primary care sites in Delaware. The innovative approach included targeted clinical interventions, population health strategies and risk stratification for the more than 800 children enrolled in asthma registries. This nested model included 42,000 children in six identified, associated communities who could be impacted by broader, community-based systems and changes in policy.

The model included collaboration with housing agencies, public health, Early Care and Education providers, schools and other community partners such as the Delaware chapter of the American Lung Association. To operate the model, Nemours employed navigators to work at the individual level and

community health liaisons to work at a systems level to identify and mitigate issues within the community, such as reducing bus idling, which exacerbates asthma, and reducing asthma triggers in public housing and in child care. The work of the community liaisons, which included collaborating with community partners through the establishment of community leadership teams and community asthma action plans, was critical to improving population health within the context of community needs that go far beyond the walls of the health system. Preliminary findings from the independent evaluator indicated reductions in the number of ED visits and hospitalizations for participants in the Nemours program relative to the comparison group.ⁱ

Recommendations:

1. Based on our experience as a HCIA awardee, we see a need for a focus on culture change and practice transformation within the health care system. Moving from volume to value necessitates buy-in and commitment from senior leadership, health care providers and non-clinical staff. It can entail new delivery models, the inclusion of different types of providers (as was the case for our Innovation Center award) and a realignment of incentives. As the Innovation Center continues to test new models, we recommend flexibility in the allowable use of funding and expressly allowing model participants to devote funding to support practice transformation.
2. As health care providers begin to gain experience with new models of care focused on improving health and reducing costs, and especially as they increasingly take on risk for their patient population, there will be an inevitable need to look beyond the walls of the clinic. We have been encouraged to see the Innovation Center testing models with a focus on improving population health through the HCIA and the Accountable Health Communities (AHC) models. We recommend that the Innovation Center continue testing models that address the social determinants of health and the medical neighborhood concept, including allowable uses of funds to support infrastructure investments in robust data sharing systems that allow multidirectional data sharing among health and social services systems.
3. Moreover, we recommend testing of two-generation models that address social determinants impacting children and families, with an emphasis on building parenting skills. Parents play a crucial role in the upbringing of their children, impacting their well-being and long-term health trajectory. Fostering strong, positive relationships between parents and children during the early years of child development can increase a child's physical and emotional health, helping them to become successful adults who contribute and integrate successfully into society.^{ii, iii, iv} We encourage CMS to consider further testing evidence-based parenting interventions and other two-generation approaches, which if shown to be effective, might be scalable more broadly through Medicaid (similar to the creation of the Medicare Diabetes Prevention Program Expanded Model^v).
4. Finally, we recommend that CMS work with the Innovation Center to determine how to best streamline data collection and reporting requirements for awardees to create less of a burden while still ensuring collection of the most important information.

Medicaid

As discussed above, Nemours recommends that CMS focus resources on addressing the underlying social determinants of health and testing two-generation approaches within Medicaid. CMS should clarify to states the ways in which they can promote two-generation approaches to improve the health, well-being and development of the child and family. For the prenatal period up to 12 months after the birth of the child, mother and baby should be treated as a unit—the mother-baby dyad. If a

mother is anxious, stressed or depressed during pregnancy, the child is at increased risk for multiple problems including emotional issues, ADHD, conduct disorders, and impaired cognitive development.^{vi} Risky behaviors during pregnancy including alcohol and drug use and smoking can increase a child's risk of fetal alcohol spectrum disorders (FADS) and sudden infant death syndrome.^{vii} FADS can lead to intellectual and developmental disabilities, behavioral issues, and disorders of the heart, kidneys, bones, and hearing. The quality of the mother's diet during pregnancy also has a large impact on positive fetal outcomes.^{viii} In addition, fostering strong, positive relationships between parents and children during the early years of child development can increase a child's physical and emotional health, helping them to become successful adults that can contribute and integrate successfully into society.^{ix,x,xi}

Recommendation:

1. We recommend that CMS use State Medicaid Director letters, Informational Bulletins and other policy guidance to highlight existing authority to provide coverage for services to the mother, as well as allow flexibility in waiver requests from states to allow them to design payment and delivery models that improve the health of the child and parent. For example, the state of Washington's Medicaid program reimburses for the evidence-based Triple P parenting program for specified services provided by a pediatrician, a pediatrician's assistant or a nurse practitioner trained and certified to deliver Triple P.^{xii} Additionally, state Medicaid agencies are permitted to cover maternal depression screening as part of a well-child visit for Medicaid-eligible moms and non-Medicaid eligible mothers because such screenings are for the direct benefit of the child.^{xiii}
2. We recommend piloting of payment models to address emerging issues, such as the increased incidence of prenatal exposure to opiates.^{xiv} Neonatal abstinence syndrome (NAS) occurs when a baby is exposed to drugs in the womb before birth and can go through drug withdrawal after birth. CMS could collaborate with SAMHSA, HRSA and other agencies to develop a core set of Medicaid-reimbursable services for NAS identified newborns and their families. This should include wraparound services, as well as reimbursement strategies for providers and specialized care coordinators/case managers, followed by an independent evaluation to determine effectiveness and replicability of the interventions.

II. Information Exchange and Meaningful Use

Nemours has long embraced health IT as a key driver in improving access to health care, quality and safety, lowering costs and enhancing the patient/family experience. Through NemoursOne, our fully integrated, system-wide Electronic Health Record (EHR) platform, we have connected and coordinated all phases of care for our patients: in our hospitals, primary or specialty care settings, and at the referring physician's office. We are leveraging our EHR to achieve national patient safety goals, improve clinical decision support, and facilitate better patient outcomes in obesity prevention, reducing asthma-related emergency department visits and increased immunization rates. Additionally MyNemours, our secure, online patient/family portal, enables parents and guardians 24/7 access to the most current health information and the ability to conveniently request, or in some cases schedule, an appointment, renew prescriptions, send photos of their child and communicate directly with the care team.

We made these investments because we believe interoperable technology and information exchange are vital underpinnings of payment reform and health care delivery transformation. Achieving a health care system that improves health outcomes by paying for value and promoting accountability is not possible without the support of reliable and accessible data. Yet, significant barriers to information exchange remain.

Barriers to Information Exchange: Policy and Regulation

In most cases, the regulatory environment, including agency policies, shapes business, clinical and cultural practices. As a result, it is critical that the right policy and regulatory incentives are in place at the state and federal level. Our experience has led us to believe that current policies and regulation misalign incentives to achieve various national health care goals, most often between the fee-for-service payment model and information sharing requirements. Such misalignment is the greatest barrier to seamless information exchange.

As long as the fee-for-service payment model persists, the health care system has little incentive to achieve robust and free-flowing information exchange because it is currently more profitable to “hoard” clinical information and resist efforts to reduce duplication of services. However, as a health care system such as Nemours moves toward a value-based payment model, information exchange and care coordination become increasingly attractive, as accountability will be based on improved clinical outcomes, thus creating an incentive to exchange information with other providers.

In the current state, however, interoperability is often the path of most resistance. The level of effort and resources required for information exchange is not justifiable in many cases. One significant challenge for provider organizations like Nemours is the variability of privacy laws governing information sharing. Our health system, like many others, operates across state lines, requiring us to navigate multiple state regulatory environments. Some states defer to Health Insurance Portability and Accountability Act (HIPAA) and others set standards higher than HIPAA. Without a comprehensive guide to help providers organizations understand their responsibilities under multiple layers of regulation (federal and state), the prospect of seamless exchange dims significantly. Moreover, interoperability is very costly (staff resources, technology upgrades or workarounds, and time), thus diminishing the value proposition when so many resources must be invested just to establish simple sharing or cross-institutional collaboration.

In addition, there is a systemic bias toward large systems with resources, such as Nemours. Primary care providers in small practices, for whom there is an increased pressure and direction to become the patient gatekeeper and coordinator, are often among those in most need of exchanged patient data, but they often cannot afford robust systems or the IT support to use them. Additionally, this shifts the cost burden to larger health systems like Nemours to fund Health Information Exchanges (HIEs) and other exchange models. For example, large organizations are often relied upon to test and troubleshoot exchange issues with the HIT of smaller practices because their staff does not have the technical expertise to do so. In other cases, organizations like Nemours engage directly with the HIT vendor of the small practice to overcome obstacles.

Finally, while we do not posit that the majority of interoperability barriers are due to a lack of existing technology solutions, we do note that vendor-to-vendor interoperability is extremely important. More standardization is needed among health records so that information can be easily translated from one system to the other. The openness and design necessary for cross-platform

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integration is not part of the traditional business model for long-standing health technology vendors. Given the positive revenue impact that federal support (through Meaningful Use) has had on EHR vendors, the federal government could set more prescriptive expectations for technology to support “plug-and-play” interoperability. Without vendor-to-vendor compatibility, full interoperability will be difficult to achieve.

Recommendations:

1. While Medicare has shown a willingness to move toward value-based payment models, Medicaid and private payers have been much slower to act. We recommend CMS and Congress accelerate this process of testing and incentivizing value-based models in Medicaid (as opposed to requiring) to promote interoperability and benefit other aspects of health care. Nemours' recommendations on value-based models can be found in Section I of this letter.
2. Create a national opt-out policy (wherein patients would actively choose to disallow their information from being exchanged through HIEs) in order to support interoperability and alleviate the barriers presented by inconsistent state opt-in/opt-out laws. Such a policy should preserve exceptions for certain sensitive information such as behavioral health data.
3. CMS and the Office of Civil Rights (OCR) should encourage and support state efforts to develop targeted, standard guidance related to state law preemption of HIPAA in an effort to clarify regulatory responsibility for provider organizations.
4. We recommend CMS and ONC require vendors to create products with the underlying intention of information sharing with other vendor products, also known as “plug-and-play” interoperability. The current certification process, governed under the Office of the National Coordinator for Health IT (ONC) is not an effective measure of interoperability, nor does it effectively test products' ability to interoperate.

Meaningful Use

Nemours credits the Meaningful Use (MU) program for pushing the industry forward by spurring positive developments in health information exchange. Many of our providers have come to rely on their ability to obtain patients' outside records through the EHR and use this information to assist in the care of their patients.

Since the inception of the Meaningful Use program, significant shifts in the American health care system have and continue to occur. One example key to the discussion on MU is the consolidation of the health care market, particularly of independent practices. We have found that consolidation has happened at a much greater rate in the adult market than in the pediatric market and, as a result, many independent pediatric practices in our markets are still using primitive technology or lack staffing and resources to utilize their technology. As a result, most small practice pediatric providers cannot receive the information we would like to exchange, making exchange impossible and negating the potential value of MU exchange requirements. In fact, given the requirements for MU, this reality has had measurable impact on our Eligible Physicians' (EPs') ability to achieve certain information exchange measures, resulting in measure failure and potential loss of incentive funds.

Another challenge we face is that some hospitals participating in MU have chosen not to staff technology capabilities that exceed the minimum necessary requirements for MU attestation. In other words, they are “checking the box” but not earnestly integrating the intent of MU into their workflow, nor are they incorporating information we send into their patient's EHR. We believe the reason behind the majority of these cases is the lack of a clear value proposition for providers to fully

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integrate information exchange into their workflow. We comment extensively on this subject in the previous section. However, as it relates to MU, it is important that CMS understand the constraints that well-intended and compliant hospitals and providers face when the culture of health care system has not fully shifted to accept the underlying premise of MU, which is, in part, to improve care coordination as well as population and public health.

With these challenges in mind as we approach Stage 3, Nemours and many other pediatric institutions project that we will be unable to meet the requirements and therefore are very unlikely to participate. Part of the challenge is elevated thresholds for hospitals and EPs attesting to Medicaid, which are not aligned with Medicare requirements. In addition, the current timeline for Stage 3 is untenable. Nemours does not believe there has been enough success across the industry in Modified Stage 2 to proceed to Stage 3.

Recommendation:

1. We recommend CMS delay MU Stage 3 and align the Medicaid measure thresholds with those in Medicare/MIPS.

Conclusion

Once again, Nemours commends CMS for the opportunity to comment on this request for information. Please do not hesitate to reach out if we can be of further assistance as this work moves forward. If you have any questions, please contact Katie.boyer@nemours.org or daniella.gratale@nemours.org.

Sincerely,



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ⁱ <https://downloads.cms.gov/files/cmml/hcia-diseasespecific-thirdannualrpt.pdf>

ⁱⁱ Center on the Developing Child. 2010. *The Foundations of Lifelong Health Are Built in Early Childhood*. Harvard University. www.developingchild.harvard.edu.

ⁱⁱⁱ National Research Council and Institute of Medicine. (2004). *Children's health: The nation's wealth*. Washington, DC: The National Academies Press.

^{iv} Marmot, M. (2010). *Fair society, healthy lives: Strategic review of health inequalities in England post-2010*. <http://www.marmotreview.org/>

^v <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/>

^{vi} Talge NM, Neal C, Glover V. Antenatal maternal stress and long-term effects on child neurodevelopment: how and why? *Journal of Child Psychology and Psychiatry* 2007;48(3-4):245-61.

^{vii} <https://www.nichd.nih.gov/health/topics/preconceptioncare/conditioninfo/pages/healthy-pregnancy.aspx>

^{viii} Fowles ER. What's a Pregnant Woman to Eat? A Review of Current USDA Dietary Guidelines and MyPyramid. *The Journal of Perinatal Education*. 2006;15(4):28-33. doi:10.1624/105812406X151394.

^{ix} Center on the Developing Child. 2010. *The Foundations of Lifelong Health Are Built in Early Childhood*. Harvard University. www.developingchild.harvard.edu.

^x National Research Council and Institute of Medicine. (2004). *Children's health: The nation's wealth*. Washington, DC: The National Academies Press.

^{xi} Marmot, M. (2010). *Fair society, healthy lives: Strategic review of health inequalities in England post-2010*. <http://www.marmotreview.org/>

^{xii} <https://www.ncbi.nlm.nih.gov/pubmed/27498167>

^{xiii} <http://www.aapublications.org/news/2016/06/21/MaternalDepression062116>

^{xiv} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3589586/>