

July 24, 2015

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

ATTN: CMS-2390-P

Re: **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**

Dear Administrator Slavitt:

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to respond to the proposed rule issued by the Department of Health and Human Services' (HHS) Centers for Medicare & Medicaid Services (CMS) related to Medicaid managed care plans.

NFPRHA is a national membership organization representing the nation's publicly funded family planning providers – nurse practitioners, nurses, administrators, and other key health care professionals. NFPRHA's members operate or fund a network of nearly 5,000 health centers and service sites that provide high-quality family planning and other preventive health services to millions of low-income, uninsured, or underinsured individuals in 50 states and the District of Columbia. Services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers and other private non-profit organizations.

NFPRHA appreciates the strong commitment of CMS to modernize the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. We offer these comments to clarify important protections for low-income women and men in need of and seeking family planning and sexual health services through Medicaid managed care plans, and

to further improve access to confidential, high-quality care from qualified family planning providers.

CMS should clarify the policies, processes, and oversight necessary for effective utilization of Medicaid’s freedom of choice protections for family planning.

We appreciate that CMS has consistently confirmed that Medicaid enrollees are entitled to freedom of choice for family planning, and that CMS has reaffirmed this commitment in the proposed regulations. The Medicaid Act guarantees that family planning services must be “furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies.”¹ States must ensure that “each beneficiary is free from coercion or mental pressure and free to choose the method of family planning to be used.”²

The right of enrollees to freely choose to receive family planning services from any qualified participating provider is an essential protection designed to ensure that women and men have ready access to the health services they need when they need them, and from a provider they trust. The freedom of choice provision also ensures that enrollees can obtain all family planning services and supplies and all family planning-related services that are covered by the state plan, regardless of whether a particular service or supply is covered by the Managed Care Organization (MCO), Pre-paid Inpatient Health Plan (PIHP), Pre-paid Ambulatory Health Plan (PAHP), or Primary Care Case Manager (PCCM) entity.

The proposed regulations provide an important opportunity to clarify the policies, processes, and oversight necessary for effective utilization of Medicaid’s freedom of choice protections, to ensure individuals are able to freely access family planning services and supplies free from coercion and other barriers that can impede their rights under law.

§ 438.10(g) – Information for enrollees of MCOs, PIHPs, PAHPs and PCCM

entities—Enrollee handbook: We support CMS’s proposal to replace the current information standards section in order to provide better clarity to beneficiaries and to better reflect current technology advances that provide access to information more quickly and less expensively. Medicaid’s freedom of choice protections mean little if enrollees do not know a) they have the ability to seek services from the provider of their choice, and b) how they can obtain those benefits. We therefore recommend that subsection (2)(vii) of § 438.10(g) be amended as follows:

(vii) The extent to which, and how, enrollees may obtain benefits, ~~including family planning services, and supplies,~~ from out-of-network providers, **including informing enrollees of their right to obtain family**

¹ 42 U.S.C. § 1396d(a)(4)(C).

² 42 C.F.R. § 441.20.

planning services and supplies and family planning–related services from any Medicaid provider without limitation or prior authorization.

§ 438.60 – Prohibition of additional payments for services covered under MCO, PIHP or PAHP contracts: We support the requirement that states must ensure that “no payment is made to a network provider other than by the MCO, PIHP, or PAHP for services covered under the contract between the State and the MCO, PIHP, or PAHP” except as required by law. States have an obligation to ensure access to all covered services under the state plan, and to ensure adequate and timely payment to providers for any services covered under the state plan but not covered under a managed care plan’s contract. Freedom of choice requires that the state ensure that all enrollees can access family planning services and supplies and family planning–related services, and that providers are reimbursed in a timely and adequate manner.

§ 438.68 – Network adequacy standards: Although freedom of choice is a vitally important protection for Medicaid enrollees and providers, it should be noted here that it is not an adequate substitute for the in–network inclusion of safety–net family planning providers, as will be discussed later in these comments. Being in–network allows a provider to be better integrated into the continuum of care, better situated to share records, referrals and resources, and better positioned to secure adequate reimbursement rates and timely reimbursement, all of which benefit enrollees, managed care plans, and state and federal governments.

§ 438.106 – Liability for payment: Ensuring that enrollees can choose their method of family planning free from coercion and from the provider of their choice requires that enrollees not be charged for family planning services and supplies and family planning–related services provided outside of the managed care network, even when a specific service or supply is not covered by the managed care plan. Federal law has long required states to cover family planning services and supplies, without any copayments or other patient cost sharing.³ The Affordable Care Act (ACA) has expanded these protections under Medicaid, requiring that individuals newly eligible for Medicaid through ACA Medicaid expansion have access to a wide array of preventive health services without cost sharing, including all FDA–approved contraceptive methods, counseling, and visits; sexually transmitted infection (STI) and cervical cancer screening; human papillomavirus (HPV) vaccinations; and many other services.⁴ Even if a managed

³ 42 U.S.C. 1396o(a)(2)(D).

⁴ The ACA requires that people newly eligible for Medicaid because of the ACA’s Medicaid expansion are enrolled in so–called alternative benefit plans (ABPs), which are required to include the ACA’s essential health benefits (EHB). The EHB

care plan does not cover the full range of family planning and related services enrollees are entitled to receive, the state has an obligation to ensure such services are accessible without any patient cost sharing.

We therefore recommend adding a new subsection (d) to § 438.106 to clarify that enrollees who receive family planning services and supplies and family planning-related services out of network cannot be charged for such services and supplies covered by the state plan but not covered by the enrollee's managed care plan. We recommend the new subsection read as follows:

(d) Family planning services and supplies and family planning-related services obtained out of network, whether or not the service is covered under the enrollee's MCO, PIHP, or PAHP.

§ 438.206 – Availability of services: We strongly support the requirement that states “must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs in a timely manner,” and that the MCO, PIHP, or PAHP must cover out-of-network services in an adequate and timely manner. Timely and adequate reimbursement to out-of-network providers for all family planning services and supplies and family planning-related services covered by the state plan, even when such services and supplies are not covered by the enrollee's managed care plan, are critical to ensuring enrollees' ability to access services freely through the family planning providers of their choice.

We therefore recommend that CMS explicitly affirm in this section that enrollees have the right to seek family planning services from out-of-network providers for any reason, regardless of whether an in-network provider is available and without the need for a referral, pursuant to the Medicaid Act's freedom of choice provisions. We recommend CMS make clear that enrollees are entitled to all family planning services and supplies and family-planning related services that are covered under the State plan regardless of whether they are covered by the MCO, PIHP, PAHP, PCCM, or PCCM entity. We further recommend that the regulations specify that states must ensure that health care providers delivering family planning services out of network are reimbursed in a timely manner at a rate no less than Medicaid fee-for-service or in-network rates, whichever is greater.

includes a number of preventive services, including an array of women's preventive health services, without copays or other cost sharing.

CMS should explicitly clarify that utilization controls and medical necessity criteria may not be imposed on family planning methods or services.

We appreciate CMS's efforts to ensure that utilization controls do not interfere with an enrollee's freedom to access the full range of Food and Drug Administration (FDA)-approved family planning methods, both in the context of managed care and Medicaid fee-for-service (FFS). To ensure the final rule reflects existing law, we urge CMS to explicitly clarify in regulation that, both within managed care and FFS, utilization controls may not be imposed on family planning methods and that managed care plans cannot apply medical necessity criteria to an individual's request for family planning services.

The intimate nature of family planning care necessitates each individual being able to access the birth control product she or he needs, taking into account the individual's medical history, lifestyle, and personal preference, all of which are essential to maximizing method efficacy. Federal regulations require that each enrollee be "free from coercion or mental pressure and free to choose the method of family planning to be used,"⁵ thus recognizing that an individual may require a certain birth control method and that coercion may occur if an enrollee does not have equal access to all covered birth control methods. Permitting utilization controls, such as step therapy and prior authorization, on family planning methods contravenes the regulations, as free choice is impossible unless an enrollee has unimpeded access to *all* covered methods.

In addition, from public health and health care management standpoints, utilization controls do not serve a useful purpose within the context of family planning. Utilization management is designed to avoid payment for costly unnecessary care. In recent years, Medicaid managed care entities have begun imposing utilization management on birth control products.⁶ However, it is

⁵ 42 C.F.R. § 441.20.

⁶ For example, Meridian Health Plan of Michigan requires providers to obtain prior authorization for hormonal and non-hormonal intrauterine devices (IUDs) (Mirena and ParaGard, respectively), the birth control ring (NuvaRing), and the birth control patch (Ortho Evra). The state's contract with Meridian permits the issuer to "require additional documentation, such as medical records, to justify the level of care provided," and impose "prior authorization for services for which the Medicaid FFS program does not require prior authorization." Family planning services are not explicitly exempt from the prior authorization clause. Mich. Dep't of Cmty. Health, *Change Notice No. 9 to Contract No. 071B0200013 between the State of Michigan and Meridian Health Plan of Michigan*, 161 (Oct. 1, 2012), available at http://www.michigan.gov/documents/buymichiganfirst/0200013_297847_7.pdf. Similarly, before Meridian Health Plan withdrew from New Hampshire's Medicaid program in 2014, the managed care issuer began to require prior authorization for Mirena and Skyla hormonal IUDs. Importantly, however, the prior authorization standard effectively established step therapy requirements for these IUDs by limiting coverage to: (1) patients who had menorrhagia for at least three months and experienced failure with oral contraception, and (2) patients who did not have menorrhagia but had serious contraindications to other hormonal methods and experienced failure with ParaGard (non-hormonal IUD). The FDA considers hormonal and non-hormonal IUDs unique and separate methods of contraception, and Meridian's imposition of utilization controls impaired an individual's ability to access all family planning methods and the specific needed birth control product. FDA, *Birth Control Guide*, <http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM356451.pdf>.

well-documented that family planning services are cost-effective and result in future savings.⁷ Step therapy, in particular, is illogical within the context of family planning. Step therapy intends to streamline health care delivery, reduce future health care costs, and diminish wasteful spending by requiring an individual to “try and fail” with one or more lower-cost drugs, devices, or services before accessing an alternative, pricier service. However, when applied to contraception, the “try and fail” approach could result in a woman experiencing an unintended pregnancy. Greater access to FDA-approved contraceptive methods would likely reduce costs associated with unintended pregnancy such as pregnancy complications and low birth weight infants.

While we believe CMS intends for the proposed rule to eliminate such practices and mitigate any additional barriers to family planning services, the preamble of the proposed rule sets a confusing standard by stipulating that “utilization controls are permissible so long as family planning services are provided in a manner that protects the enrollee’s freedom to choose the method of family planning to be used consistent with § 441.20.”⁸ Permitting utilization controls at all is inconsistent with the intent of § 441.20 and undermines related federal law and policy intended to secure access to a wide range of family planning services and supplies, including the administration’s recently launched Maternal and Infant Health Initiative.⁹ This is certainly not CMS’s intent and should be clarified in the final regulation.

To eliminate barriers to all covered family planning methods and ensure enrollees maintain freedom of choice of family planning methods as required under § 441.20, CMS must make it clear that utilization controls cannot be imposed on any FDA-approved contraceptive methods. Additionally, in line with this administration’s efforts to improve access to and utilization of contraception, CMS should stipulate in regulatory text that utilization controls may not be imposed on any covered family planning service or supply within a family planning method. Withholding utilization controls from all covered family planning products will safeguard an enrollee’s access to the family planning service of her or his choice and ultimately advance CMS’s goals to improve contraceptive access, improve quality health outcomes, and reduce future health care costs.

Furthermore, we disagree with CMS’s statement in the preamble that states and plans have the “ability to apply medical necessity criteria for an individual’s request for family planning

⁷ American taxpayers save more than seven dollars for every dollar spent on publicly funded contraception. In 2010, the availability of publicly funded contraception resulted in a net savings of \$13.6 billion. Jennifer J. Frost et al., Guttmacher Inst., *Return on investment: A fuller assessment of the benefits and cost savings of the US publicly funded family planning program* (Oct. 2014), available at http://www.guttmacher.org/pubs/journals/MQ-Frost_1468-0009.12080.pdf.

⁸ 80 Fed. Reg. 31098, 31138 (Jun. 1, 2015).

⁹ 42 U.S.C. §§ 1396d(a)(4)(C), 1396u-7(b)(5); 42 C.F.R. § 440.347(a) (requiring Medicaid benchmark and benchmark-equivalent coverage to include family planning services and supplies); 78 Fed. Reg. 42160, 42195 (Jul. 15, 2013) (stipulating that Medicaid ABP standards must maintain freedom of choice of family planning provider and free choice of family planning methods).

services but provides that utilization controls that would interfere with an enrollee's freedom to choose the method of family planning would not be permitted."¹⁰ Given the individualized nature of these services, enrollees must be absolutely free to choose the methods of family planning that will work best for them, without any restriction. The distinction that CMS attempts to draw in the preamble between medical necessity criteria and utilization controls is unworkable—by definition, family planning services are medically necessary for enrollees of child-bearing age who desire them. CMS should clarify in the final regulation that plans cannot impose any form of prior authorization or medical management requirements on family planning services beyond a cursory assessment to confirm that the enrollee is of child-bearing age and desires family planning services.

Moreover, CMS should note that provider access is integral to an enrollee's ability to access family planning services. Individuals are unable to obtain the family planning service of their choice if they are not able to access such service from a trusted family planning provider in a timely manner. As such, we urge CMS to adopt a comprehensive approach in improving contraceptive care and make sure the final rule promotes access to family planning providers while also ensuring coverage for all covered family planning services and supplies without barrier.

CMS should strengthen network adequacy requirements to ensure enrollees have timely access to family planning and sexual health services and providers.

Current Medicaid regulations require plans to maintain a network of providers sufficient to meet the health care needs of enrollees, and to reimburse those providers well enough to achieve that goal. However, such network adequacy requirements provide little in the way of protections specific to family planning providers. As of 2010, only 40% of safety-net health centers providing family planning services had any contracts with Medicaid plans.¹¹ Beyond family planning, two inspector general reports highlighted serious deficiencies in states' network adequacy standards, oversight and enforcement, and serious problems on the ground, including inaccurate provider directories, large numbers of providers not accepting new patients and long waiting times for appointments, especially for specialists.¹²

¹⁰ 80 Fed.Reg. 31138.

¹¹ Rachel Benson Gold and Adam Sonfield, *Working Successfully with Health Plans: An Imperative for Family Planning Centers*, New York: Guttmacher Institute, 2012, <http://www.guttmacher.org/pubs/health-plans.pdf>.

¹² Office of the Inspector General, *State Standards for Access to Care in Medicaid Managed Care*, Washington, DC: Department of Health and Human Services, 2014, <http://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf>; Office of the Inspector General, *Access to Care: Provider Availability in Medicaid Managed Care*, Washington, DC: Department of Health and Human Services, 2014, <http://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>.

The proposed regulations include welcome steps to address some of the current problems with network adequacy, including new requirements at § 438.68 for states to set standards. We have several recommendations for strengthening these requirements and ensuring enrollees' timely access to the full range of covered services.

We are pleased that CMS will, for the first time, require states to employ specific measures of travel time and distance to determine whether the networks of their contracted plans are adequate. We commend CMS for delineating in § 438.68(b)(1) the provider types for which states must develop geographic access standards. However, much stronger standards are needed to ensure that enrollees can access the full range of reproductive health care services. In the preamble, CMS notes that it considered, but opted against, adding family planning providers to the list of providers subject to time and distance standards, and requests comments on that decision. We strongly urge CMS to reverse that decision. Freedom of choice, while a critical protection, is not a substitute for a network of providers that can meet the unique health needs of their women enrollees. Being in-network allows a provider to be better integrated into the continuum of care, better situated to share records, referrals and resources, and better positioned to secure adequate reimbursement rates and timely reimbursement. And this is particularly important under Medicaid for safety-net family planning providers, because they serve 44% of poor women nationwide who obtain contraceptive care.¹³ In short, having safety-net family planning providers in-network is beneficial for enrollees, providers and plans, and that should be reflected in the network adequacy standards.

CMS's narrow focus on OB/GYNs will fail to ensure the adequacy of a plan's network to ensure that women have meaningful access to all covered family planning and abortion services. The final regulations should include network adequacy standards that encompass not only access to OB/GYNs, but to the full range of family planning and sexual health providers, which includes nurse practitioners, certified nurse midwives, physician assistants, and other non-physician practitioners. Moreover, MCO plan networks must not only ensure access to specific types of providers, but also to the full range of covered services, and the minimum network adequacy standards should reflect that. Many reproductive health services are both time sensitive and, in many places, in limited supply. We urge CMS to amend § 438.68(b)(1) to specify that network adequacy standards must incorporate waiting times for initial appointments for time-sensitive services, specifically family planning services and supplies. Timely access to appointments is critical, as any delay in accessing family planning can lead to an unintended pregnancy.

The ACA's requirements for private health plans offering coverage on the new marketplaces to contract with essential community providers (ECPs)—specified types of safety-net providers, including family planning health centers, that serve low-income patients—is a model that could

¹³ Jennifer J. Frost, *U.S. Women's Use of Sexual and Reproductive Health Services: Trends, Sources of Care and Factors Associated with Use, 1995-2010*, New York: Guttmacher Institute, 2013, <http://www.guttmacher.org/pubs/sources-of-care-2013.pdf>.

strengthen network adequacy standards for MCOs. These safety-net providers have historically been indispensable to meeting the needs of Medicaid enrollees, and therefore the ECP standards should be stronger for Medicaid than those that apply in the private sector. Specifically, CMS should require Medicaid MCOs to solicit contracts for all ECPs in their service areas and to contract with any ECP that is willing. Such contracts must be offered for all of the covered services an ECP provides and on generally applicable contract terms, including reimbursement at generally applicable rates.

Additionally, we support the requirement at § 438.68(d) that states must individually evaluate and approve any request by an MCO for an exception to network adequacy standards; without strong oversight, an exceptions process can severely undermine seemingly strong standards. As part of demonstrating network adequacy, including under any approved exceptions, MCOs must be required to address enrollees' need for care when in-network providers are not available within the state's standards. That might happen by facilitating access to out-of-network providers, providing transportation services or providing access via telemedicine.

We also commend CMS for requiring plans to publish their network adequacy standards in § 438.68(e). We agree that this is an area where transparency is very important, and consumers, providers, advocates, and other stakeholders must have ready access to the standards to which plans are being held. We suggest that CMS also compile this information and publish it on Healthcare.gov or Medicaid.gov on an annual basis, since many stakeholders may look for this information on a federal government website rather than looking for the website for their state Medicaid program.

CMS should ensure direct access to women's health services providers.

Another key protection under Medicaid is the requirement that MCOs provide direct access to women's health providers. To ensure that this access standard is robust, which ensures women can access essential family planning and sexual health services from providers they trust, we recommend that CMS make three clarifications to § 438.206(b)(2). First, CMS should make it clear that the direct access protection applies to women of all ages, including adolescents. We do not believe CMS intends adolescents to be excluded from the group of female enrollees who can have direct access to a specialist for these services, and we suggest that it say so explicitly to avoid any confusion. Second, we ask that CMS replace "women's health specialist" with "women's health services provider." This change ensures that the full range of reproductive health care providers, which includes OB/GYNs, nurse practitioners, certified nurse midwives, physician assistants, and other non-physician practitioners, will be accessible to Medicaid managed care enrollees. Third, we ask that CMS replace "women's routine and preventive health care services" with "the full range of family planning and sexual health services." We are concerned that limiting direct access to "women's routine and preventive health care services"

will encourage plans to place barriers that will impede enrollee's access to the family planning and sexual health services long required by the Medicaid program without cost sharing. Depending on how individual plans define it in specific circumstances, "women's routine and preventive" health care services could inappropriately limit enrollee's access to a wide range of needed care provided as part of a visit to a women's health services provider.

CMS should strengthen protections for enrollee confidentiality, particularly as it relates to family planning and other sensitive services.

Confidential access to family planning and other sensitive services has long been the standard of care in public health, and is critical to ensuring patients seek out essential health services. Lack of confidentiality, or concerns about confidentiality, can prevent women and men from seeking services out of fear that a parent, spouse, or partner might find out, putting them at risk of physical or emotional harm.

The need for confidentiality protections has evolved with technology and the expansion of coverage under the ACA, presenting myriad ways confidentiality can inadvertently be breached, particularly in the Medicaid managed care context. These may include mailings from Medicaid managed care or other insurers, access to health information through insurer-patient portals, or other Medicaid mailings, none of which are adequately protected by the Health Insurance Portability and Accountability Act (HIPAA). Patients and providers need approaches and policies that allow for both the use of Medicaid managed care coverage and the maintenance of privacy throughout the insurance claims process. The proposed Medicaid managed care regulations present an important opportunity to address some of these needed approaches and policies, including:

Overarching confidentiality protections: Medicaid managed care plan enrollees deserve strong confidentiality protections beyond just the protection of patient medical records. While ensuring the confidentiality of medical records is crucial, particularly in the current era of electronic data breaches both within and outside of the insurance industry, the need to protect patient confidentiality extends far beyond an individual's medical record. In the family planning and sexual health context, the services received by the enrollee, and even the visit itself, need to not be disclosed in order to protect enrollees from the potential for physical or emotional harm. Furthermore, patients have to know, understand, and be able to use these protections for them to have any meaning.

Medicaid managed care plans must implement and utilize effective systems to safeguard enrollee confidentiality, such as the creation of effective processes to protect confidentiality throughout the claims process. States have an obligation

to monitor and enforce confidentiality protections and to make sure managed care plans are implementing such systems. CMS should also query states about potential points of confusion about interpreting federal rules, and provide them with greater clarity and technical assistance when needed.

Communications to enrollees: Managed care enrollees deserve the right to information about the services they receive. At the same time, managed care plans' communications concerning sensitive services ("services" here includes any health care services and/or supplies provided, the provider from which such services and/or supplies were received, as well as the visit in which the services and/or supplies were provided) must not place the patient who received those services at risk of harm.

The HIPAA Privacy Rule creates a floor of privacy protections, protecting and providing access to patients' health information and records—referred to as "protected health information" or PHI.¹⁴ But the Rule also makes allowances to release information for "treatment, payment, or health care operations" without patient authorization. In practice, this means that confidential patient information, which the health care provider has ethical and legal obligations to protect, moves rapidly in the health care market. PHI is shared among insurers, health care providers, and others, with the potential of being included in a bill, an explanation of benefits (EOB), or other communication in ways that can unintentionally disclose private information to people other than the patient. Although the Privacy Rule requires health plans and health care providers to allow patients to request restrictions on the disclosure of their PHI, they are generally only required to comply with such requests if either a) they agree to do so, or b) the disclosure is not otherwise required by law and the information pertains to health care that has been fully paid for by the patient or someone other than the health plan. Additionally, HIPAA's endangerment clause, which allows patients to request that communications such as EOBs be redirected to an alternative address or sent by an alternative means, requires only that plans and providers accommodate "reasonable requests" and allows health plans to require individuals to state that they would be endangered by disclosure. What constitutes a reasonable request, and what is considered endangerment—including what is required to demonstrate such danger—vary widely between states and insurance plans.

Thus, even though the Privacy Rule provides some measure of protection for Medicaid managed care enrollees, these protections are not sufficient in the context of family planning and other sensitive services. Plans must make clear to

¹⁴ 45 C.F.R. Part 160 and Part 164, Subparts A and E.

enrollees what types of communications they will be using, and the circumstances under which and frequency of such communications. This information should be shared with Medicaid providers to enable them to help enrollees evaluate how to best ensure enrollees' confidentiality throughout the claims process.

States must ensure Medicaid managed care plans provide all enrollees—regardless of age and without limitation based on circumstance (e.g. requiring that the enrollee is a victim of intimate partner violence)—the ability to redirect communications about their coverage to an alternate physical or electronic address.

Third-party liability/good-cause exception: Federal statutes and regulations provide a good-cause exception to the requirement that individuals identify and provide information to assist in the pursuit of third parties who may be liable to pay for care and services under the plan when “it is anticipated that cooperation will result in reprisal against, and cause physical or emotional harm to, the individual or other person.”¹⁵ However, this exception was written at a time when the primary means for a state Medicaid program to identify potentially liable third-party payers was through information provided by the patient; if a patient claimed the exemption and did not provide their health insurance information, they could be reasonably assured that other payers—which may send EOBs or other communications that could breach the patients' confidentiality—would not be billed, and therefore their privacy would be protected.

However, in today's age of electronic records and databases, and with the expansion of commercial health insurance coverage through the health insurance exchanges created through the ACA, many states now have alternate ways to identify and bill potential third-party payers, often without notice to the enrollee or health care provider. The good-cause exception should be updated to reflect modern electronic database and billing realities in order to protect enrollees at risk of physical or emotional harm when billing a third-party payer may breach the enrollee's confidentiality.

Further, states must ensure Medicaid enrollees and managed care plans are informed of federal confidentiality protections, including the good-cause exception, and have systems in place to ensure that managed care plans and any third-party payers interacting with managed care plans maintain enrollees' confidentiality throughout the claims process.

¹⁵ 42 U.S.C. § 1396k; 42 C.F.R. § 433.147.

Enrollment protections: Just as the release of information about a health care visit, provider, or services received has the potential to cause harm to an enrollee, so does the release of information about an individual's enrollment in Medicaid coverage. As states have invested in technology to better use enrollment data and as diverse databases containing information about enrollees become more linked, the risk that information will be released has increased. For example, confidentiality could be breached when a state attempts to ease enrollment and renewal under Medicaid using information about enrollment in other state assistance programs. Another example stems from the processes used to determine eligibility for coverage under the ACA; if appropriate safeguards are not in place, a parent seeking to enroll the family in coverage could inadvertently be notified that their child or spouse is already enrolled in coverage that individual uses for family planning services, putting the individual at risk of harm.

Applicants who need to access care should be able to apply for, enroll in, and use coverage without undue burden and with appropriate safeguards to prevent confidentiality from being breached, including during the claims process. Consistent with existing law regarding the good-cause exception, states must ensure their eligibility and enrollment procedures permit an applicant to withhold information about third-party payer sources, including information about a policyholder with third-party payer coverage.

CMS should strengthen provider non-discrimination protections.

We appreciate CMS reiterating existing provider discrimination protections in regulation at § 438.12, as well as providing an additional provider non-discrimination standard at § 438.214(c) to prohibit a managed care entity from discriminating against providers that serve high-risk populations or specialize in conditions that require costly treatment. However, these standards still provide managed care entities considerable discretion to evaluate health care providers on non-merit based standards. We urge CMS to strengthen the provider non-discrimination standard at § 438.12 by establishing clear requirements that prevent managed care entities from outright excluding or limiting the participation of qualified health care providers. Specifically, we urge CMS to amend § 438.12 to prohibit a managed care entity from discriminating against an otherwise qualified health care provider on the basis that the provider furnishes certain services under their scope of practice (including abortion), on the basis of the patients they serve, or on the basis of the professional activity or advocacy they conduct separate from their contractual relationship with the managed care entity or participation in the state's Medicaid program. Likewise, CMS should require that agreements between Medicaid managed care plans and participating providers reinforce this critical standard.

A stronger provider non-discrimination standard ensures that each managed care plan does not exclude, terminate, provide insufficient reimbursement rates, or otherwise restrict or coerce a health care provider's ability to practice care that is legally permitted under state law; furnish services that comply with national standards of care, recommendations, or other protocols; and engage with professional membership organizations or participate in other health care-related activities that advocate for or recommend changes to medical protocols or the broader health care system. In line with CMS's ultimate goal to improve patient access to high-quality care, establishing a strong non-discrimination protection in regulation and managed care provider agreements will help safeguard and bolster provider participation in Medicaid managed care and ensure health care provider participation is squarely rooted in a provider's ability to deliver quality care that improves health outcomes.

CMS should clarify and strengthen states' responsibility for ensuring enrollees have access to the full range of family planning and sexual health information, services, referrals, and providers.

Access to and coverage of all services when an entity objects to coverage

Federal law and regulations place an obligation on states to ensure that enrollees have coverage for and timely access to all Medicaid services—even if some services are carved out of an MCO contract or are unavailable in an MCO's provider network—and that enrollees know about their rights and how to access needed care. The rules around this requirement are complex, particularly for enrollees, and it is not clear that they are working well in practice. States' responsibility for ensuring that enrollees have access to the full range of covered sexual and reproductive health information, referrals, services, and providers should be clarified and strengthened. Our recommendations are as follows:

§ 438.10(e) – Current regulations require the state merely to provide a summary of the services covered by each MCO, while the proposed regulations would seem to bolster the information states need to provide. However, that section should be strengthened further by requiring information not only about counseling and referral excluded by an MCO because of moral or religious objections but about all services excluded for such reasons. CMS should also retain language from current regulations (which has been cut in the proposed regulations) that requires potential enrollees to be informed not only about services covered by the state (rather than by the MCO) but also “how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.”

§ 438.10(g) – More should also be done to address problems faced by individuals after they have enrolled. At § 438.10(g), MCOs' enrollee handbooks are required to include

information about counseling and referral excluded by an MCO because of moral or religious objections, and how enrollees may obtain information about such counseling and referral from the state. As we recommend above for potential enrollees, this information requirement for enrollees should extend to all services excluded because of moral or religious objections. Moreover, to facilitate timely and accurate information about excluded services, we recommend that states be required to establish a toll-free hotline and an online portal through which enrollees could learn how and where to obtain needed care not covered by plans, and to require MCOs and providers to direct patients to those resources whenever a specific need arises (not merely through the handbook).

§ 438.52 – We recommend that new language be included making it clear that even when a state restricts a potential enrollee’s choice of MCO plans, the available options must always include at least one plan that includes the full range of reproductive health services covered by the state’s Medicaid program. No Medicaid enrollee should be required to enroll in a plan that limits access to care because of moral or religious objections. Similarly, the regulations should prohibit Medicaid enrollees from being passively enrolled in such a plan.

In addition, the protections at § 438.52(b) related to religious objections—currently written to apply only to rural area residents—should be extended to all enrollees. Specifically, all Medicaid enrollees must be allowed out-of-network access whenever “the only plan or provider available to the beneficiary does not, because of moral or religious objections, provide the service the enrollee seeks” and whenever “the beneficiary’s primary care provider or other provider determines that the beneficiary needs related services that would subject the beneficiary to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.”

§ 438.102(b)(2) – As proposed, § 438.102(b)(2) incorporates the requirement in § 438.10(g)(2)(ii)(B) that a managed care entity inform enrollees how they can obtain information from the state about how to access a counseling or referral service that the entity does not cover by reference. However, we are concerned that the text of that provision could be somewhat misleading, as it only explicitly states that MCOs, PIHPs, and PAHPs do not have to inform enrollees and potential enrollees how and where to obtain excluded counseling or referral services. In addition, as discussed above, we are concerned that § 438.10(e)(2)(v)(C) does not require that a managed care entity provide potential enrollees with information about how they can obtain information from the state about how to access a counseling or referral service that the entity does not cover. This omission is reflected in § 438.102(b)(2), as proposed. We ask that CMS amend § 438.102(b)(2) to explicitly state that MCOs, PIHPs, and PAHPs must inform enrollees and potential enrollees how they can obtain information from the state about how to access

counseling or referral services that their plan refuses to cover for moral or religious reasons.

CMS should monitor and address problems with access to family planning and sexual health providers and services.

We thank CMS for the expanded monitoring requirements included at § 438.66, which would require states to create a monitoring system, conduct readiness reviews, and submit annual reports to CMS. We ask that CMS and states use this expanded oversight capacity to monitor and address known and potential problems with access to reproductive health services and providers. For example, multiple studies and anecdotal reports have found evidence that some MCOs are illegally charging cost sharing for family planning services, or are interfering with the free choice of a contraceptive method through such tactics as prior authorization and step therapy. Similarly, CMS and the states have clear reasons to be concerned about limited access to many reproductive health services, particularly when plans, providers, and facilities object to such services on moral or religious grounds. These types of issues should be prioritized by CMS and the states as they implement and make use of an expanded oversight and enforcement capacity.

CMS should ensure that safety-net providers are able to best leverage 340B-priced drugs within the Medicaid managed care context.

We appreciate CMS's efforts to properly implement and clarify rules governing the intersection of Medicaid managed care and the 340B drug pricing program administered by the Health Resources and Services Administration (HRSA). The 340B program is essential to the ability of safety-net health providers, such as the family planning and sexual health providers NFPRHA represents, "to stretch scarce Federal resources as far as possible, to reach more eligible patients and provide more comprehensive services."¹⁶ We believe the proposed managed care regulations present an important opportunity to address critical 340B-related issues to ensure that the program continues to benefit safety-net providers and the vulnerable populations they serve. Accordingly, we will be separately submitting comments concerning our 340B-related concerns as they relate to the proposed managed care rule.

¹⁶ H.R. Rep. No. 102-384(II), at 12 (1992).

NFPRHA appreciates CMS's efforts to update the Medicaid managed care regulations and the opportunity to comment on the proposed rule. If you require additional information about the issues raised in this letter, please contact Robin Summers at 202-286-6877 or at rsummers@nfprha.org.

Sincerely,

A handwritten signature in cursive script that reads "Clare M. Coleman". The signature is written in a dark ink and is positioned to the left of the typed name and title.

Clare Coleman
President & CEO