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RE: CMS-9914-P: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations

The National Health Council (NHC) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Benefit and Payment Parameters for 2022 under the Patient Protection and Affordable Care Act (the Proposed Rule).

Created by and for patient organizations 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 140 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations. The following is our specific response to the details of the proposed rule.

Since enactment and implementation of the Patient Protection and Affordable Care Act (PPACA), the NHC has recognized that its long-term viability depends on the stability of the individual health plan marketplaces and meaningful outreach, engagement,

and communication throughout the enrollment processes. We continue to support policies that promote market stability while aligning with our primary commitment to ensuring that individuals with chronic conditions and disabilities have access to affordable, high-value, sustainable health care. Our comments, therefore, focus on ensuring that all Americans, particularly those with chronic diseases and disabilities, can access the health care they need at a cost they can afford.

The COVID-19 pandemic has reinforced the societal imperative that all people need access to adequate and affordable health insurance coverage. The Centers for Medicare & Medicaid Services (CMS) has, since the early months of the COVID-19 Public Health Emergency (PHE), focused its efforts and expertise on ensuring that our health care system has the tools and flexibilities needed to respond to the unprecedented demands of the pandemic. While the availability of vaccines and new treatment modalities offer real hope that resolution of this PHE is in sight, uncertainties and challenges remain with respect to the short- and long-term impact of the pandemic on employment, health, and access to health coverage. It is, therefore, more important now than ever that future coverage under the PPACA align with three overarching principles:

- Health care must be adequate. Health care coverage should cover treatments patients need, including the services in the essential health benefit package;
- Health care should be affordable. It should enable patients to access the treatments they need to live healthy and productive lives; and
- Health care should be accessible. Coverage and enrollment should be easy to understand, not pose a barrier to care, and benefits should be clearly defined.

As CMS considers the finalization of policies related to the 2022 PPACA plan year, we urge it to prioritize the financial, physical, and mental health of the American people ensuring that quality health insurance coverage is adequate, equitable, affordable, and accessible. Specifically, the NHC:

- Supports CMS' proposed amendments to the special enrollment period policy and offers recommendations to strengthen enrollee access to coverage that best suits their needs;
- Urges a special enrollment (SEP)- eligibility-determination approach that reflects and responds to determination errors over a pre-set 75 percent standard;
- Opposes CMS' proposal to reduce marketplace user fees;
- Opposes changes to the Premium Adjustment Percentage Index (PAPI) and Maximum Annual Limitation on Cost-Sharing, also known as maximum out-of-pocket(MOOP), that would result in financial burdens for patients;
- Supports CMS' proposals to ensure calculations of medical loss ratio (MLR) exclude drug rebates and price concessions, and to facilitate transparency through pharmacy benefit manager (PBM) reporting requirements;

- Strongly urges CMS to withdraw its proposal to permit states to implement Direct Enrollment mechanisms without submitting an application for a Section 1332 waiver;
- Opposes CMS' proposed codification of the 2018 guidance interpreting Section 1332 guardrails; and
- Urges CMS to return to its earlier position on Copay Accumulators and Maximizers to distinguish between products with and without generic competition.

The NHC supports CMS' proposed amendments to the special enrollment period policy and offers recommendations to strengthen enrollee access to the coverage that best suits their needs.

The NHC appreciates CMS' recognition of existing challenges in SEP illuminated by COVID-19 and generally supports the proposed policy refinements that take into account the real-world experience of individuals and families facing financial and employment changes impacting their ability to retain meaningful health coverage. We agree that refinements to SEP eligibility are consistent with the overarching public policy goal of protecting the health of American families through access to high-quality, affordable health coverage. We generally support CMS' provisions that:

- Enable flexibilities on plan selection for SEP enrollees who are newly ineligible for Advance Premium Tax Credits (APTC);
- Expand SEP eligibility to enrollees that do not have timely notice of a triggering event; and
- Expand SEP eligibility for enrollees previously relying on employer contributions to COBRA continuation coverage.

Below, we offer specific recommendations to clarify and strengthen these proposals.

Improving Newly APTC-Ineligibility Policy to Allow Patient Choice in Plan Selection

We agree that individuals who become newly APTC-ineligible face important decisions with respect to choosing a plan that may involve balancing the premium cost with the breadth of coverage and overall costs within various metal levels. We expect that, absent CMS' proposed flexibility, healthier individuals and families would likely choose lower metal levels and may decline enrollment in a qualified plan, while those with health concerns would be highly motivated to retain coverage, and they may find a higher metal level more affordable if it comes with a lower out-of-pocket maximum. Moreover, extending flexibility to enroll in a plan that is at ***either*** a higher or lower metal level would not introduce increased risk of adverse selection. It would not, therefore, justify limits on enrollees' ability to choose the plan that best suits their needs. **We urge CMS to implement this SEP policy refinement to permit newly APTC-ineligible enrollees to use their SEP to enroll in a plan that best suits their needs, without limitations based on metal level.**

The NHC similarly urges CMS to ensure that newly APTC-ineligible enrollees are clearly informed that a special enrollment period is available and that they may enroll in a different metal level plan. This notification should be provided at the time of an APTC-ineligibility determination and should also provide these enrollees with the basis for the determination. Enrollees for whom ineligibility was determined based upon information that does not reflect their current financial situation must have a meaningful opportunity to challenge the determination and be informed of the required next steps and documentation needed for a reconsideration or new APTC determination. For these enrollees, the SEP period should not expire until 60 days after a notice of a final determination of APTC ineligibility.

Strengthening COBRA Discontinuation SEP Policy

Finally, we appreciate CMS' recognition that individuals enrolled in COBRA continuation coverage with the financial support of their previous employer would face significant financial hardship in maintaining that coverage if employer contributions were no longer available. The NHC appreciates that CMS has sought feedback on whether a reduction that falls short of entirely ceasing contribution toward COBRA continuation coverage should enable SEP eligibility. **We urge CMS to prioritize “affordability” as the determining factor over employer action.** If, for example, the employer contribution is reduced from 100 percent to \$50.00 per month, there may be little distinction between that change and a complete withdrawal of the employer contribution. The seminal factor should be whether the change in contribution renders the premium unaffordable to the enrollee with respect to their monthly income. The NHC believes that this is consistent with the policies driving identification of triggering events for SEP eligibility.

The NHC urges an SEP-eligibility-determination approach that reflects and responds to determination errors over a pre-set 75 percent standard.

CMS proposes that beginning with plan year 2024, all exchanges must conduct eligibility verification for at least 75 percent of new enrollments through SEPs for consumers not already enrolled in exchange coverage. Exchanges will, under the proposal, have flexibility to determine the type of SEPs for which eligibility verification is performed and verification methods and mechanisms.

The NHC supports efforts to ensure the integrity of eligibility determinations, including those related to SEP enrollments of individuals not previously enrolled in a qualified health plan. We feel this is crucial to maintain the important balance of the risk pool, keeping premiums affordable for all. However, we are concerned the policy proposed by CMS would create an unnecessary administrative burden on individuals who qualify for an SEP

CMS has also proposed to waive enforcement of the random sampling requirement for exchange determinations of APTC eligibility. We agree that low employer response rates to these random verifications can overburden exchanges with manual verification processes. We also expect that the economic downturn caused by the COVID-19

pandemic is likely to create a higher number of SEP enrollments adding to the burden. ***We therefore support CMS' proposal to waive the requirement through the 2022 plan year and urge you not to enforce these requirements until additional research can be conducted to ensure that the policy does not create an undue burden on individuals, particularly those with serious and/or chronic conditions.***

If CMS chooses to pursue such policies, prior to its implementation, CMS should conduct research to:

- Ensure selection of SEP types for verification does not place a higher burden on enrolled individuals with complex care needs or deter their enrollment through SEPs;
- Consider adjusting the threshold for eligibility verification if verification experience yields a low level of enrollment errors. This would enable exchanges to reallocate those resources to improve efficiencies; and
- Permit exchanges to use prior years' SEP enrollments as a basis for calculating the verifications necessary to meet the applicable threshold. This will permit exchanges to distribute their verification activities throughout the year and avoid situations in which over- or under-estimates in SEP enrollment drive end-of-year verification activities.

The NHC opposes CMS' proposal to reduce the marketplace user fees.

CMS proposes to reduce user fees applicable to plan enrollment through the federal exchange to 75 percent of the current rate and to implement a deeper cut for state operated exchanges to 70 percent of the current rate. CMS also proposes to introduce a new category of user fees that would be applicable to states electing to use a Direct Enrollment mechanism that is significantly below the user fee to plans offering coverage in states maintaining enrollment through PPACA exchanges. As explained later in this letter, the NHC opposes the use of Direct Enrollment.

The marketplace user fees are essential to funding exchange operations, including maintenance of exchange websites and portals, navigator programs, education and outreach, and plan management functions. The NHC is concerned that reducing funding to exchanges will compromise the quality and quantity of information available to individuals as they determine which health insurance plan best suits their needs. The PPACA's Navigator Program, for example, is an important resource for Americans seeking to make informed decisions about which health insurance plans best fit their needs. We have previously opposed the series of funding cuts that have likely deterred organizations from continuing to serve as Navigator entities and expect that user fee reductions will result in even more limited access for consumers needing in-person assistance to choose a plan and complete enrollment.

The NHC has significant concerns that funding constraints will disproportionately impact individuals with complex care needs, including those with disabilities. Similarly, outreach

and enrollment funding has historically been used to help disadvantaged populations, such as helping those with limited English proficiency understand their plan options and how to enroll. In previous years, CMS lessened training requirements for Navigator programs by replacing a set of 20 specific training topics with broad categories. As funding decreases, we anticipate that Navigator training will be aligned with plan financial concerns rather than the needs of those seeking enrollment assistance. Similarly, the NHC has previously expressed concern that the outreach and education activities in advance of each plan year's enrollment period have not sufficiently informed potential enrollees of their options and the applicable deadlines for enrollment. In addition, outreach and enrollment activities are critical to addressing health coverage disparities among underserved and underrepresented populations. Further restricting the ability of navigators to provide service to these communities, we will continue to see growing disparity.

We urge CMS to withdraw its proposal to reduce user fees so that the exchanges have sufficient funding to respond to the uncertain demand for PPACA qualified plan coverage, enrollment information, and plan selection assistance likely to emerge at resolution of the current PHE.

The NHC opposes changes to the Premium Adjustment Percentage Index (PAPI) and Maximum Annual Limitation on Cost-Sharing (MOOP) that would result in financial burden for patients.

The 2022 NBPP proposes to increase the PAPI in accordance with the revised calculation methodology adopted in 2019. We continue to oppose these changes. The proposed 2022 premium adjustment percentage reflects an increase of about 6.4 percent over the 2021 percentage. A higher premium adjustment means higher required contributions from consumers by decreasing premium tax credit amounts. Thus, this continued and accelerating growth under the new methodology shifts ever-greater costs onto families. The limit on total out-of-pocket expenses will likely be \$400 higher for individuals and \$800 higher for families than they would be absent the 2019 methodology change. Increased marketplace premium and out-of-pocket costs will disproportionately impact lower-income individuals and those with higher health care needs. Facing these enormous costs, some individuals may choose to forgo necessary care, leading to costly and dangerous complications.

The 2022 NBPP proposed rule would also increase the cap on annual maximum out-of-pocket (MOOP) payments for qualified health plans (QHPs) by 6.4 percent. As a result of changes to the PAPI that were codified in the 2021 NBPP, this threshold is increasing more quickly than in prior years, resulting in greater cost-sharing obligations for enrollees. The proposed change to the premium measure will also result in faster growth in net premiums paid by consumers on the marketplaces and a faster growth in the MOOP limit paid by all Americans, including those with large group employer coverage. We are concerned that rising out-of-pocket costs will result in more

Americans foregoing medically necessary services, leading to worse health outcomes and more uncompensated care costs, especially for those with pre-existing conditions.

A growing number of Americans are underinsured, therefore experiencing difficulty paying the out-of-pocket costs associated with care, including deductibles, copays, and coinsurance. This holds true for a cross-section of Americans, including those with large group employer coverage as well as those with individual coverage, and it is an especially pressing concern for people with chronic health conditions. For these reasons, we urge CMS to return to its previous method of calculating the PAPI in order to reduce the out-of-pocket burden on consumers.

The NHC supports CMS' proposals to ensure calculations of medical loss ratio (MLR) exclude drug rebates and price concessions, and to facilitate transparency through Pharmacy Benefit Manager (PBM) reporting requirements.

The NHC strongly supports policy changes and refinements that strengthen requirements on qualified plans to meet MLR thresholds. We appreciate CMS' proposal to require that plans deduct the value of rebates and any other drug-related price concessions from costs associated with incurred claims beginning with the 2022 MLR reporting year. The definition of "rebates and price concessions" to include those received or receivable by *both* insurers and PBMs is an important step toward ensuring that qualified plans meet an MLR threshold that accurately reflects the funds actually expended on health care items and services.

CMS also has proposed to implement requirements directing PBMs to report data to both CMS and the qualified health plan for which the PBM is providing services. The NHC views this new reporting requirement as an important step toward increased transparency into the financial arrangements between manufacturers, PBMs, and QHPs. We believe CMS needs to receive this information directly to ensure its accuracy. Qualified plans will be able to use these data to ensure discounts are appropriately passed to enrollees, and PBM performance aligns with high-quality coverage.

The NHC generally supports CMS' proposed definition of rebates and price concessions to include "discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." We recommend, however, that the term "coupons" be removed from the definition as coupons are not generally within the set of discounts and price concessions extended to either PBMs or qualified health plans. For the most part, coupons are offered to consumers and redeemed at the point of sale; the value of these coupons may not be known or knowable by plans or PBMs and they are used to reduce drug-related costs incurred by individual consumers.

We also note that CMS excludes “bona fide service fees” from its definition of discounts. While we agree that service fees should not be subtracted from drug costs as if they were discounts, we oppose their inclusion in calculating MLR. As CMS acknowledges in its proposal, insurers and PBMs are likely to adjust their contracts to accommodate the proposed policy refinements, and increased transparency and clear exclusion of drug-related discounts from MLR could significantly reduce revenue streams the parties consider or rely upon in setting the parameters of their arrangements. The NHC is concerned that enabling inclusion of “bona fide service fees” in MLR calculations could incentivize greater use of service-fee-generating activities such as medical review, prior authorization, step therapy protocols, claim appeals, and other functions that have more to do with impeding or denying care than covering its costs. We urge CMS to specifically clarify that PBM fees to qualified health plans are administrative costs that must be excluded from MLR calculations.

The NHC strongly urges CMS to withdraw its proposal to permit states to implement Direct Enrollment mechanisms without submitting an application for a Section 1332 waiver.

On November 1, 2020, CMS approved an application for waiver of certain PPACA requirements under Section 1332 of the Social Security Act submitted by the state of Georgia. The CMS proposal to enable states to elect to implement Direct Enrollment (DE) mechanisms follows the general contours of Georgia’s DE waiver. The proposal, however, goes beyond general guidance on CMS consideration of future state DE waiver requests, with CMS waiving portions of Section 1311 of the PPACA generally, and of its own accord. Our concerns with this proposal are both procedural and substantive.

From the procedural standpoint, the NHC has significant concerns that CMS’ proposal would exempt future DE mechanisms adopted by states from the Section 1332 notice and comment requirements and statutory guardrails that were applicable to the specifics of Georgia’s adoption of this mechanism. The Section 1332 waiver process provides a set of guardrails that deter states from pursuing policies or objectives that run afoul of statutory requirements, including development of a clear, actionable plan, stakeholder engagement, and opportunity to gain feedback, and CMS review of state reports on their progress. We believe the Section 1332 waiver authority establishes an inherent government oversight function and set of responsibilities, as well as public notice and comment requirements, that CMS cannot divest itself (or the states) from through policy change or regulation.

From a substantive standpoint, the NHC has significant concerns that moving away from a centralized marketplace toward enrollment through insurers and web-brokers will adversely impact potential enrollees seeking information and enrolling in health coverage that fits their needs and goals. While we understand CMS’ interest in reducing uncertainty for states seeking to waive provisions of the PPACA, the DE proposal is likely to inject confusion and uncertainty for individuals and families seeking to enroll in

coverage. In its 2020 plan year proposed rule, CMS noted that even good faith efforts of web-brokers to inform consumers about the distinctions among QHP types can cause confusion and lead consumers not to select an on-exchange QHP even when they qualify for an APTC. This reason alone underscores the importance of a functioning, integrated exchange administered through a governmental or nonprofit entity, subject to federal oversight. In addition:

- Although DEs may provide consumers with “a broader array of plan options,” including on- and off-exchange plans as well as ancillary products, enrollees may not fully understand they are not using an “exchange” or that some plans may not provide essential health benefits.
- Relying on DE entities as the only enrollment mechanism severely complicates enrollment for individuals who are eligible for Medicaid or CHIP. The private DE entities will be unable to direct enrollees to these programs, and CMS does not appear to require the entities perform this important function.
- CMS proposes allowing the use of qualifying web-broker websites to help consumers enroll in coverage. CMS had previously concluded that assisters would be unable to use a web-broker website consistent with an assister’s duty to provide fair, accurate, and impartial information. Eliminating the role of exchanges in enrollment in favor of DEs exacerbates this concern. Individuals who would benefit from an assister are unable to reliably access the help they need to enroll in a plan that best suits their needs.
- CMS proposes to permit DEs to operate for the first 12 months without providing translations into languages commonly used within their communities. The NHC expects that the significant changes to enrollment options and presentation format within a DE model, coupled with serious concerns on the availability and impartiality of “assisters,” will make it nearly impossible for individuals to enroll in a qualified health plan unless they are fluent in written English. This delay will only increase the disparity in access to coverage.

The NHC has previously expressed concern with web brokers servicing non-PPACA-compliant plans and displaying those offerings alongside qualified health plans. The expansion of available options, including short-term, limited-duration (STLD) plans, and elimination of the exchange platform enrollees have customarily used, will inject confusion on scope and breadth of coverage for the various plan types. We are concerned brokers may be incentivized to sell these plans, and consumers will not have a clear understanding about what STLD plans do and do not cover, or the differences between marketplace coverage and STLD plans.

We request CMS withdraw its DE proposal. The Section 1332 waiver mechanism is available to any state seeking to implement a DE alternative for QHP enrollment. The opportunity to observe Georgia’s experience with this alternative to a centralized exchange will enable CMS, providers, insurers, and consumers to gain an understanding of best practices, vulnerabilities, and patient protection safeguards

needed to ensure consumers, particularly those with chronic diseases and disabilities, retain access to the affordable, high-quality health coverage they need.

The NHC opposes CMS’ proposed codification of the 2018 guidance interpreting Section 1332 guardrails.

The NHC views Section 1332 of the PPACA as striking a balance between state flexibility to tailor insurance reforms to improve the well-being of their residents, and the unambiguous statutory directive to maintain the levels of benefits, affordability, and coverage required under the PPACA. We have historically supported 1332 waivers that aim to facilitate access to comprehensive coverage and enhance the sustainability of insurance marketplaces such as reinsurance programs. We have, however, grown increasingly concerned with waivers that are intended to promote the proliferation of subpar coverage or otherwise undermine the PPACA marketplaces. However, when CMS released its 2018 Guidance entitled “State Relief and Empowerment Waivers,” the [NHC urged](#) for its withdrawal. Specifically, we stated that the policies contained in the Guidance could adversely impact the risk pool and erode the PPACA’s protections for individuals with pre-existing conditions and that State waivers that promote purchase of non-compliant coverage could confuse consumers and leave them susceptible to being significantly under-insured.

We continue to believe that the Guidance falls short of protecting people with pre-existing conditions and has the potential to cause them great harm. We urge CMS to withdraw the proposal and decline to codify the State Relief and Empowerment Waivers Guidance.

The NHC urges CMS to return to its earlier position on Copay Accumulators and Maximizers to distinguish between products with and without generic competition.

The NHC remains concerned about the increasing use of copay “accumulator” and “maximizer” programs. CMS’ position on the use of these programs has changed over the past two years, and we ask the Agency, once again, to re-examine its position. The current system subjects patients to high out-of-pocket costs over the course of the plan year, particularly for drugs used to treat complex and chronic conditions. Patients requiring branded medications without an available generic substitute often rely on copay coupons, discount cards, charitable assistance, and other assistance as the only means to afford the medication they need. This has become an urgent problem for patients unable to obtain needed treatment during the current pandemic.

The NHC had [supported](#) CMS’ 2020 NBPP provision to permit plans and issuers to exclude any form of direct manufacturer cost-sharing support from calculations toward applicable annual limitations on out-of-pocket costs ***only when offered for a specific brand prescription drug that has a generic equivalent.*** There is a clear distinction between these instances and those where there is no generic equivalent, and the 2020 NBPP struck the right balance between eliminating inappropriate use of copay coupons

and allowing assistance to help people afford their needed medications. The NHC continues to believe that the 2020 NBPP policy represents a pragmatic, nuanced approach to eliminating inappropriate use of copay discount cards and other direct manufacturer assistance.

Conclusion

We appreciate the opportunity to provide input on the proposed changes impacting health coverage under the PPACA. Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

A handwritten signature in cursive script that reads "Eleanor M. Perfetto".

Eleanor M. Perfetto, PhD, MS
Interim Chief Executive Officer and
Executive Vice President, Strategic Initiatives