February 21, 2013

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-2334-P
P.O. Box 8016
Baltimore, MD 21244-8016

To Whom It May Concern:

The National Viral Hepatitis Roundtable appreciates the opportunity to comment on the proposed rule regarding Essential Health Benefits (EHB) standards in Medicaid Alternative Benefits Plans, Medicaid cost-sharing, and Exchange and Medicaid eligibility and appeals processes. We thank you for your commitment to implementing the Affordable Care Act (ACA) in ways that ensure access to viral hepatitis prevention, care, and treatment. As HHS finalizes the regulations for implementing the Medicaid expansion and the eligibility notification and appeals process, we urge you to consider the ACA's intent to end the discriminatory practices of insurers and to increase access to meaningful health care coverage.

Medicaid expansion through ACA implementation offers tremendous hope and opportunities to uninsured, low-income people who have chronic hepatitis B or C. To provide meaningful health coverage and reduce geographic health disparities, a high national standard must be set for comprehensive prescription drug coverage, preventive services, chronic disease management services, and mental health and substance use disorder services. Such services must be available without prohibitive cost-sharing, which acts as a significant barrier to care for low-income people, and without discriminatory restrictions and limits. Ensuring that Medicaid works is critical for people living with chronic viral hepatitis to be diagnosed early, linked to and retained in regular care and treatment and realize the lifesaving benefits of treatment.

With this in mind, we strongly urge HHS to consider the following:

"Alternative Benefit Plan" (ABP) for Medicaid

We appreciate the description of the state process to select an ABP that meets both Essential Health Benefits (EHB) requirements and complies with existing § 1937 rules. As we read the proposed rule, any ABP that a state selects must comply with the EHB standards of a private insurance benchmark plan (after that plan is supplemented with any missing categories). If the ABP choice is also one of the EHB private insurance benchmark options, the plan is automatically deemed to be in compliance with the EHB requirements and if the ABP chosen differs from the private insurance EHB, a comparison to ensure coverage of the ten categories is necessary. However, we urge HHS to clarify the following:

- ***State Selection of ABP***
  We urge HHS to clarify that states may design an ABP that is very similar to their traditional Medicaid coverage package (for instance, by using the flexibility described in 42

CFR § 440.360 to add a range of existing Medicaid services to an ABP) as long as the ABP includes the ten categories of EHBs measured against a private insurance EHB benchmark. We have concerns in the proposed rule implementing the EHB requirements for the private insurance market regarding lack of specificity for the benefits categories. Without adequate definitions of critical benefits categories for people living with chronic viral hepatitis and other chronic conditions – for instance, mental health and substance use disorder services or chronic disease management – there is concern that states will have little basis on which to assess proposed plans to assure that the EHB requirements are met.

We also urge HHS to clarify the flexibility that states will have to design multiple ABPs targeting specific populations. We understand this provision to allow states to put in place ABPs for sub-populations within the newly eligible group (for instance, people living with chronic viral hepatitis or other chronic conditions) and urge HHS to clarify that this is an appropriate use of the ABP flexibility.

- ***Non-discrimination mandates for ABPs***
  We appreciate the inclusion of a non-discrimination mandate in § 440.347(e) ("Essential health benefits cannot be based on a benefit design or implementation of a benefit design that discriminates on the basis of an individual's age, expected length of life, an individual's present or predicted disability, degree of medical dependency, or quality of life or other health condition.") However, **to ensure that the non-discrimination requirements for Medicaid populations are no less robust than the non-discrimination requirements articulated for provision of EHB in the private insurance realm, we urge HHS to explicitly include the other non-discrimination mandates that attach to the private insurance EHB requirements:**
    - EHB must "reflect an appropriate balance among the categories" (ACA, § 1302(b)(4)(A));
    - The Secretary may "not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life" (ACA, § 1302(b)(4)(B));
    - EHB must "take into account the health care needs of diverse segments of the population, including women, children, [and] persons with disabilities" (§ 1302(b)(4)(C)).

Taken together, these protections ensure that people living with chronic viral hepatitis and other vulnerable populations are protected from plan designs that systematically bar access to medically necessary care and treatment through service exclusions and limits, utilization management techniques, and cost-sharing. In developing analyses to assist federal and state regulators in identifying discriminatory practices and ensuring compliance with the non-discrimination provisions, we urge HHS to explicitly define how the following criteria should be implemented by the states and how they will be monitored and enforced by HHS:

- Medical necessity requirements for Medicaid must be evaluated and standardized, and HHS should monitor state implementation of medical necessity to ensure that people living with chronic viral hepatitis and other chronic and complex conditions have unimpeded access to essential care and treatment.

- Utilization management techniques, exclusions, and service limits must be closely monitored to ensure that plans have not put in place barriers to services or excluded or limited certain items or services solely to deny access to care for people with chronic and complex health conditions. We urge HHS to develop a list of practices that amount to discrimination to help guide monitoring and enforcement activities. For instance, requiring step therapy for chronic hepatitis B or C treatment without a medical override provision is a discriminatory utilization management technique that should be barred. Similarly, a monthly limit on prescription drugs (e.g., several states have monthly limits of three or four prescription drugs) is also per-se discriminatory, as applied to people living with chronic viral hepatitis and other chronic conditions.

- ***Benefits requirements for ABPs***
  We appreciate discussion of how existing Medicaid benefits requirements and rules interact with EHB requirements. However, we urge HHS to clarify how the EHB requirements affect the following Medicaid services:

  - Prescription drug coverage
    We support the proposal to apply the rules governing coverage of prescription drugs under Medicaid (§ 1927 of the Social Security Act) to the ABP that requires coverage of nearly all of the drugs produced by manufacturers who participate in the Medicaid drug rebate program. The breadth of coverage offered by the Medicaid drug benefit is important to meet the medication needs of people with chronic hepatitis B or C. However, we have serious concerns regarding the flexibility afforded to states to apply quantitative limits on drug coverage, particularly given that these limits are not common practice in the private insurance market. Allowing these types of limits in ABPs threatens access to lifesaving care and treatment and undermines the letter and spirit of the ACA's EHB requirements for newly eligible Medicaid beneficiaries.

    To meet the spirit and intent of the ACA, it is imperative that the non-discrimination protections found in § 440.347(e) are strictly and clearly applied to the ABP prescription drug benefit. Quantitative limits on the number of prescription drugs covered per month are discriminatory against people with chronic viral hepatitis and others whose quality of life and health depend on access to a specific regimen of multiple prescription drugs to treat both hepatitis and co-occurring conditions as recommended by their medical provider. **The application of the non-discrimination provisions should prohibit states from applying quantitative limits on monthly drug coverage for the expansion population, and we strongly urge that this standard also be applied to the traditional Medicaid population. If monthly drug limits are considered, there must be provisions to allow for a timely override process that does not delay immediate and uninterrupted access to the medications when recommended by a medical provider.**

  - Preventive services
    We strongly support inclusion of the preventive services requirements described in § 2713 of the ACA as a required component of Medicaid ABPs. These services will include hepatitis B screening of pregnant women. They will also include hepatitis C

screening for at-risk individuals if the recently USPSTF proposals for a Grade B is approved.

However, we are extremely concerned that other preventive screenings recommended by the Centers for Disease Control and Prevention (CDC) will not be included. These include one-time screening for hepatitis C for all baby boomers (those born between 1945-1965), who make up the overwhelming majority of hepatitis C cases in the country, and hepatitis B screening for at-risk individuals, particularly those born in geographic regions with high hepatitis B prevalence or those with parents born in one of those region. We strongly urge inclusion of all CDC hepatitis B and C screening recommendations as required components of Medicaid ABPs.

We are also concerned by the proposal to allow cost-sharing for preventive services for low-income populations when these services will be available without cost-sharing for higher income individuals in the private insurance market. We strongly believe that there should be parity between the private insurance and Medicaid EHB definitions for this category of services.

We also support the proposed provision in § 440.130 that will allow non-physician providers to provide these preventive services when *recommended* by a physician or other licensed practitioner provider rather than exclusively provided by a physician/licensed practitioner. Because hepatitis B and C testing is often performed by a range of community-based providers, allowing greater flexibility for non-physician providers to receive reimbursement for these services will greatly expand access to these services. This will be especially important to low-income people who disproportionately access care through community-based and support services and may experience significant stigma and lower trust levels with other providers.

- ***Exempt populations from automatic placement in ABPs***
  We strongly support explicit application of the § 1937 list of populations exempt from automatic placement in an ABP to the newly eligible Medicaid population. These protections are essential to ensuring that people living with chronic viral hepatitis and other chronic conditions are able to access the Medicaid benefits package that best meets their care and treatment needs. In particular, we support proposed clarifications to the definition of "medically frail" to include individuals with "serious and complex medical conditions." We urge HHS to clarify that chronic viral hepatitis (for example, especially for those who may living with other co-morbidities ***or*** advanced liver disease) are serious and complex medical conditions for purposes of the exemption. We also strongly urge that HHS explicitly include individuals with a substance use disorder as qualifying in the definition of medically frail. Future guidance, application instructions, and enrollment processes will be necessary to ensure that people who qualify as medically frail are able to choose the benefits plan that best meets their needs. We envision situations where it may be beneficial for a medically frail individual to have access to an ABP rather than the traditional Medicaid package, and urge HHS to design processes that ensure these individuals have the ability to make an informed choice about their Medicaid benefits options.

- ***Public notice requirements***

We appreciate explicit inclusion of a public notice requirement in § 440.386 of the proposed rule, requiring state plan amendments implementing an ABP to be publicly shared. However, we are concerned that the proposed very short (two week) time period required for public comment does not support a meaningful opportunity for stakeholder input. In the spirit of transparency, we also urge HHS to require that all state plan amendments are shared prior to state submission to CMS for approval, not just in situations where the proposed ABP provides fewer benefits than the current state plan.

- ***Reevaluation of EHB definition approach in 2016***
  We appreciate inclusion of language indicating the intent of HHS to reevaluate its EHB framework in 2016. At this time, we strongly urge HHS to adopt a new process both for defining EHB and for ensuring meaningful stakeholder involvement at both the state and federal levels. Specifically, we urge HHS to move away from a benchmark model, which enshrines current disparities and geographic variation into the insurance market. Instead, HHS should adopt an approach that sets a higher and clearly defined national standard for benefits coverage that meets the care and treatment needs of people living with chronic viral hepatitis and other chronic conditions. We also urge HHS to consider more robust stakeholder engagement in the process used to assess the current EHB approach and whether to adopt a new approach in 2016.

Medicaid Cost-sharing and Premiums

Cost-sharing can provide a significant barrier to care, particularly for low-income people with chronic conditions who, on average, use more health care services. Numerous studies have shown that even nominal cost-sharing obligations for this population can deter people from accessing the care and treatment that they need to stay healthy. While we appreciate and support efforts to simplify and streamline Medicaid cost-sharing rules, we are very concerned that the new flexibility afforded to states in setting cost-sharing levels will harm people with chronic viral hepatitis and others who rely on regular access to multiple medical providers and services, including prescription drugs.

We are particularly concerned by the proposal to allow states to charge up to $8 for a non-preferred drug for individuals with income less than or equal to 150% of the federal poverty level (FPL) and up to 20% of the cost of the drug for individuals with income over 150% FPL. These high cost-sharing levels, even with a 5% cap on out of pocket spending, will leave lifesaving treatment out of reach for many Medicaid beneficiaries with chronic hepatitis B and C who may need multiple medications and may not have the flexibility to take the less expensive preferred medications due to their unique medical needs. As an example, an individual living with hepatitis C for example, whose income is above 150% FPL and is taking the protease inhibitor Incivek, could have co-pays as high as $2,400 per month. Even with the 5% cap on out of pocket spending, the up-front costs for this individual would be so high that it could very likely be a deterrent to starting lifesaving treatment.

Therefore, we strongly urge you to lower the upper limit allowed to maintain nominal cost-sharing levels as intended for this vulnerable population or require classes of clinical concern, such as anti-hepatitis drugs, to be available at the "preferred" drug cost-sharing level. At a minimum, it will be critical to ensure that Medicaid beneficiaries and their providers are aware that individuals with income less than 100% FPL cannot be denied services for a failure to pay and that non-preferred drugs must be made available at the preferred drug cost-sharing level if recommended by the medical provider. These

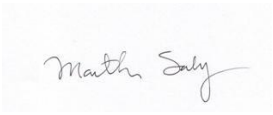
important protections are unfortunately often not effectively implemented in practice and many Medicaid beneficiaries and their providers are not aware of them.

Additionally, the proposal to increase the co-payment for non-emergency use of the emergency room to $8 for people with income under 150% FPL (§ 447.54) and allow no limit on the cost for individuals with income above 150% FPL may discourage medically appropriate use of emergency services, particularly because the definition of what constitutes "non-emergency use" is vague. It also does not take into account the reality that the average beneficiary may not be able to definitely discern between symptoms related to medical emergencies and non-emergencies. With regard to solicitation of comments on proposed changes to cost-sharing obligations for institutional care for people with income below 100% FPL (§ 447.52), we strongly support a $4 maximum. We also urge HHS to limit the cost sharing states may impose on those seeking community-based long-term services and supports. Finally, we urge HHS to clarify that the 5% aggregate cap on premiums and cost sharing applies to all individuals with income below 100% FPL.

If the cost sharing provisions for Medicaid beneficiaries are retained, we urge HHS to consider protections that would ensure low-income people living with chronic viral hepatitis and other chronic conditions have access to essential care and treatment. Here, the Medicare Part D protections with regard to cost sharing are instructive. The copayment amounts for the Low Income Subsidy available under Part D are limited to $1.10 for preferred/generic drugs and $3.30 for other medications for individuals with incomes at or below 100% FPL and $2.50 and $6.30, respectively, for individuals with incomes over 100% FPL. We recommend that HHS place a similar cap on cost sharing amounts for people living with viral hepatitis and other chronic conditions. Further, we believe that the non-discrimination protections should be strongly enforced to ensure that cost-sharing obligations do not present an insurmountable barrier to care for people with chronic viral hepatitis and other chronic conditions. Providers should be able to waive cost-sharing requirements in instances where they present a barrier to access to lifesaving services and medications for vulnerable populations.

Thank you for the opportunity to comment on this regulation. Please contact Ryan Clary, Director of Public Policy and Programs (rclary@nvhr.org), if we can be of assistance.

Sincerely,



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