

Supporting Statement - Part B

External Quality Review (EQR) of Medicaid and Children Health Insurance Program (CHIP) Managed Care, EQR Protocols, and Supporting Regulations in 42 CFR 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370 CMS-R-305, OMB 0938-0786

Collection of Information Employing Statistical Methods - The eight currently approved protocols were drafted in 2010 by Provider Resources, Inc. and the National Commission for Quality Assurance with the intention of providing updated guidance to states, their contractors that are not managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), primary care case management (PCCM) entities (described in §438.310(c)(2)), or external quality review organizations (EQROs) hired by states on how to properly conduct three mandatory and five optional EQR activities listed in 42 CFR 438.358. The regulations required the initial drafting and promulgation of these protocols in 2003; the 2012 revision incorporated changes in law and quality practices since the original version was published. CMS updated the information collection (but not the included protocols) to align with the EQR provisions of the final rule; this update was approved by OMB on June 16, 2017 with an expiration date of June 20, 2020 (ICR Reference Number 201611-0938-016). CMS updated the eight protocols in 2019 to align with the 2016 final rule; this update was approved by OMB on October 31, 2019 with an expiration date of October 31, 2022 (OMB Control Number 0938-0786).

The information collection request was last revised in 2022 with revisions to the EQR protocols, and included: (1) aligning the existing protocols, appendices, and worksheets with the 2020 final rule, and (2) adding a new protocol, Validation of Network Adequacy (RIN 0938-AS25, CMS-2390-F).

The current information collection request is not revising the current protocols. If finalized, the rules promulgated by this rulemaking (CMS 2439-P) would result in revisions to protocols.

- 1) States and/or their contractors are not required to follow these protocols exactly, but are required to use “methods consistent with the Protocols.” Taken together, the protocols could be considered to be a textbook on statistical methods in health care quality control. Often, several statistically valid methods are offered to states and/or their contractors conducting a specific EQR task. The protocols offer general statistical guidelines for states and/or their contractors to apply and do not dictate specifics. The states and territories that utilize MCOs, PIHPs, PAHPs, or certain PCCM entities are therefore required to submit Medicaid EQR technical reports.
- 2) **Procedures for collection** - See answer to number one and the enclosed Protocols. As required under 42 CFR 438.10(c)(3), the state must post its finalized annual technical report(s) on its website by April 30th of each year (proposed in CMS 2439-P to be changed to December 31). CMS also requests states submit their completed EQR technical report(s) to CMS via email each year (notifying CMS is proposed as a requirement in CMS 2439-P).
- 3) **Methods to maximize response rates and address non-response** – States are required by regulation (see 42 CFR 438.364(c)(1)) to finalize the annual EQR technical report by April 30th each year (proposed in CMS 2439-P to be changed to December 31). CMS

proactively reaches out to states to solicit annual report submission. Following initial outreach, the CMS conducts state-specific follow-up to address non-response. We work with states and/or their contractors to improve compliance and address requests for technical assistance.

- 4) **Tests of procedures or methods undertaken** - See answer to number one and the enclosed Protocols.
- 5) **Individuals consulted** – Not applicable with this information collection request, since the protocols are not being revised.