Supporting Statement - Part B External Quality Review (EQR) of Medicaid 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. The revised EQR Protocols received OMB approval in September 2012 for a three-year period, which expired September 30, 2015. On May 19, 2015, OMB renewed this PRA package without change, with an expiration date of May 31, 2018. On May 6, 2016, CMS published a final rule (RIN 0938-AS25, CMS-2390-F) to modernize Medicaid managed care external quality review provisions and apply them to prepaid ambulatory health plans (PAHPs) and certain primary care case management entities (PCCM entities) whose contracts with states provide for quality incentives (see 81 FR 27498). 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).

This information collection request presents revisions to the eight existing EQR protocols, which were last revised in 2012. The revisions to the EQR protocols include: 1) consolidation of the existing EQR protocols and associated worksheets and appendices into one document; 2) restructuring and revising the documents to simplify the narrative flow and usability; 3) updating the protocols to include current best practices; and 4) aligning the existing protocols, appendices, and worksheets with the 2016 final rule (RIN 0938-AS25, CMS-2390-F).

- 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 which 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. Currently states submit final EQR technical reports to CMS via email.

- 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. The 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** The 2012 version of these protocols were written by Provider Resources, Inc. and the National Commission for Quality Assurance (NCQA). This 2018 revision was written by Mathematica Policy Research (MPR), but are now the responsibility of the Division of Quality and Health Outcomes (DQHO) in CMS. The designated contact for DQHO is Heather Hostetler located at S2-04-27, telephone number (410) 786-4515.