Supporting Statement – Part A

Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration (CMS-10673; OMB 0938-1354)

A. Background

The Centers for Medicare & Medicaid Services (CMS) may test a demonstration, under Section 402 of the Social Security Amendments of 1967 (as amended), entitled the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration ("the Demonstration"). If it goes forward, the MAQI demonstration could test whether exempting, through the use of waiver authority, clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) (combined with participation, if any, in Advanced Alternative Payment Models (APMs) with Medicare Fee-For-Service (FFS)) from the Merit-based Incentive Payment System (MIPS) reporting requirements and payment adjustment will increase or maintain participation in payment arrangements with MAOs similar to Advanced APMs and change the manner in which clinicians deliver care.

Clinicians may currently participate in one of two paths of the Quality Payment Program (QPP): 1) MIPS, which adjusts Medicare payments based on combined performance on measures of quality, cost, improvement activities, and advancing care information, or 2) Advanced Alternative Payment Models with Medicare (Advanced APMs), under which eligible clinicians may earn an incentive payment for sufficient participation in certain payment arrangements with Medicare Fee-For-Service (FFS) and other payers, and starting in the 2019 performance period, with other payers such as Medicare Advantage, commercial payers, and Medicaid managed care. To participate in the Advanced APM path of QPP for a given year and earn an incentive payment, eligible clinicians must be determined to be Qualifying APM Participants (QPs); in addition to earning an APM incentive payment, QPs are excluded from the MIPS reporting requirements and payment adjustment.

An eligible clinician that does not meet the criteria to be a QP for a given year is subject to MIPS for that year unless the clinician meets certain other MIPS exclusion criteria, such as being newly enrolled in Medicare or meeting the low volume threshold for Medicare FFS patients, payments, or services. In the Calendar Year 2019 Quality Payment Program proposed rule, CMS is proposing to modify the definition of low-volume threshold at §414.1305 to include that beginning with the 2021 MIPS payment year, if an eligible clinician or group meets or exceeds one or two, but not all, of the low-volume threshold determinations, including as defined by dollar amount ($90,000) or beneficiary count (200), or services (minimum threshold of 200), then such eligible individual or group may choose to opt-in to MIPS. This proposed policy does not affect eligible clinicians who are above all of the low-volume threshold criteria, or otherwise not excluded, and are therefore required to participate in MIPS. Eligible clinicians who are Partial QPs for a year are

not subject to the MIPS reporting requirements and payment adjustment unless they choose to report to MIPS, but they do not earn the APM incentive payment.

The MAQI Demonstration could allow participating clinicians to have the opportunity to be exempt from MIPS reporting and payment consequences for a given year if they participate to a sufficient degree in certain Qualifying Payment Arrangements with MAOs (and Advanced APMs with Medicare FFS) during the performance period for that year, without requiring them to be QPs or otherwise meet the MIPS exclusion criteria of QPP. Under a possible Demonstration, clinicians would not have to have a minimum amount of participation in an Advanced APM with Medicare FFS in order to be exempt from MIPS reporting and payment consequences, but if they did have participation in Advanced APMs with Medicare FFS, that participation could also be counted towards the thresholds that trigger the waiver from MIPS reporting and payment consequences. In addition, the Demonstration could permit consideration of participation in payment arrangements with Medicare Advantage plans that meet the criteria to be Other Payer Advanced APMs a year before the All-Payer Combination Option is available.

In the Calendar Year 2018 Quality Payment Program Final Rule, CMS noted its intention "to develop a demonstration project to test the effects of expanding incentives for eligible clinicians to participate in innovative alternative payment arrangements under Medicare Advantage that qualify as Advanced APMs, by allowing credit for participation in such Medicare Advantage arrangements prior to 2019 and incentivizing participation in such arrangements in 2018 through 2024." (92 FR 53865)

The first performance period of the Demonstration is tentatively planned for 2018, and the Demonstration would last up to five years.

Clinicians who meet the definition of MIPS eligible clinician under QPP as defined under 42 CFR § 414.1305 would be eligible to participate in the MAQI Demonstration. Currently, MIPS eligible clinicians include physicians (including doctors of medicine, doctors of osteopathy, osteopathic practitioners, doctors of dental surgery, doctors of dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. If the definition of MIPS eligible clinician changes under future rulemaking, the Demonstration would use the updated definition to define Demonstration eligibility, as of the effective date of the new rule.

Participation would last the duration of the Demonstration, unless participation is voluntarily or involuntarily terminated under the terms and conditions of the Demonstration. For example, clinicians who didn't comply with the terms of the participation agreement or presented program integrity risks may be involuntarily terminated from the Demonstration. Participants would have the opportunity each year to submit the required documentation regarding potential Qualifying Payment Arrangements and the amount of their revenue and/or patients covered by these arrangements.

In order to conduct an evaluation and effectively implement the MAQI Demonstration, CMS

proposes to collect information from Demonstration participants on a) payment arrangements with MAOs and b) Medicare Advantage (MA) payments and patient counts. CMS would requires a new collection of this information if the demonstration moves forward as this information is not already available through other sources. Collection of this information would allow CMS to make determinations of whether Demonstration participants should receive waivers from MIPS reporting and payment consequences for a given year if they participate to a certain degree in Advanced APMs through Medicare FFS and Qualifying Payment Arrangements through MAOs. If Demonstration participants submitted information, but did not meet the conditions of the Demonstration, their participation in the Demonstration would not be terminated, but they would not receive the waivers from MIPS reporting and payment consequences. Therefore, unless they become QPs or are excluded from MIPS for other reasons, the participating clinicians would be required to submit MIPS reporting and would face the MIPS payment adjustments for the applicable year.

We are requesting approval of 2 information collections associated with the MAQI Demonstration: a) a Qualifying Payment Arrangement Submission Form and b) a Threshold Data Submission Form.

1. Data Collection for the MAQI Demonstration

a. Qualifying Payment Arrangement Submission Form

The Qualifying Payment Arrangement Submission Form would be used by Demonstration participants to request that CMS determine whether a payment arrangement with an MAO is a Qualifying Payment Arrangement under the MAQI Demonstration authorized under Section 402 of the Social Security Amendments.

The requirements for Qualifying Payment Arrangements under the MAQI Demonstration would be the same as the Other Payer Advanced APM criteria for Medicare plans under QPP as set forth in 42 CFR § 414.1420. As that regulation is amended or updated for future performance years, the amended or updated requirements in the regulation would be applied to determine if a payment arrangement is a Qualifying Payment Arrangement for the same performance year in the Demonstration. For the 2018 performance year, those standards included:

- Require at least 50% of participating eligible clinicians in a Qualifying Payment Arrangement entity to use certified electronic health record technology (CEHRT) to document and communicate clinical care;
- Base payments for covered professional services on quality measures that are comparable to those used in the MIPS quality performance category and meet the standards specified in § 414.1420(c); and
- Require participants to bear more than a nominal amount of financial risk if actual aggregate expenditures exceed expected aggregate expenditures., as described in § 414.1420(d)(1) and (d)(3).

The Demonstration's standards for minimum required financial risk would match those of QPP's All-Payer Combination Option. As of the January 1, 2018, those standards were:

Expenditure-Based Nominal Amount Standard	Revenue-Based Nominal Amount Standard
Marginal Risk of at least 30%	Marginal Risk of at least 30%
Minimum loss rate of no more than 4% and:	Minimum loss rate of no more than 4% and:
Total risk of at least 3% of the expected expenditures of the APM Entity (the "benchmark" of the Entity)	Total risk of at least 8% of the total combined revenues from the payer to the providers and other entities under the payment arrangement

In 2019 and subsequent years of the Demonstration, the Demonstration would consider Qualifying Payment Arrangements to be those arrangements with MAOs that QPP determines to be Other Payer Advanced APMs through either the Payer- or Eligible Clinician- Initiated Submission Processes[1]. Because QPP will not make Other Payer Advanced APM determinations for the 2018 performance year, Demonstration participants would be required to submit information to CMS through a separate process (i.e., the Qualifying Payment Arrangement Submission Form noted in this document) so that CMS may determine whether their payment arrangements with MAOs meet the criteria to be a Qualifying Payment Arrangement. The content of the submission is proposed to mirror the content required by CMS to be submitted for purposes of making Other Payer Advanced APM determinations, and would include:

- Name of the payer and payment arrangement
- Description of how the payment arrangement meets the requirements outlined above
- Payment arrangement documentation (e.g., contracts)

The planned submission period for 2018 Qualifying Payment Arrangement determinations is projected to be from October 24 through December 5, 2018. CMS is projecting 30 days for the submission period. CMS intends to review and provide determinations for submitted Forms in January 2019 if possible.

Calendar Year (CY) 2018 implementation of the MAQI Demonstration was limited by a very aggressive timeline, leading to limited functionality for the MAQI Portal & Data Collection tool, minimal training and educational materials for users on QPP options vs. MAQI, and modest flexibility to consider public comments. Since we are able to start implementation for CY 2019

earlier in the calendar year we are now considering improvements in these areas. The CY 2019 timeline will also provide CMS more time to review QPA/Threshold information and offer clinicians more time to submit their information. Clinicians will have 60 days to submit information in CY 2019, compared to 30 days in CY 2018.

We have heard from QPP/PRA commenters and organizations that they want TIN Level MIPS exclusion and more functionality when an organization/authorized representative is submitting on behalf of their clinicians. Based on information received from organizations we now understand how they are doing business--individual clinician are not submitting the form-- it is the organization that is submitting on behalf of their clinicians. For CY 2018 when an organization/authorized representative submits on behalf of their clinicians that organization/authorized representative would have to submit one record for each clinician. The CY 2019 enhancements that the MAQI team is proposing would address this issue and provide more functionality.

b. Threshold Data Submission Form

The Threshold Data Submission Form (Form) would be used by Demonstration participants to request that CMS determine whether they may receive waivers from MIPS reporting requirements and payment adjustments. This process is called the MIPS waiver determination process. Demonstration participants who met either the payment amount threshold or the patient count threshold shown below for at least one of three snapshots (January 1 – March 31, January 1 – June 30, or January 1 – August 31) during the performance period for a given year of the QPP would receive waivers from MIPS reporting requirements and payment adjustments for that year of QPP.

Performance period year	Payment amount threshold (percent of total Medicare FFS and MA payments that are under the terms of Advanced APMs/ Qualifying Payment Arrangements)	Patient count threshold (percent of total Medicare FFS and MA patients that are under the terms of Advanced APMs/ Qualifying Payment Arrangements)
2018	25%	20%
2019	50%	35%
2020	50%	35%
2021	75%	50%
2022	75%	50%

1 Since the information in this form will be available via other means starting in 2019, CMS is only seeking PRA approval for the collection of information in this form for 2018.

This Form collects MA payment and patient count information, for purposes of calculating payment amount and patient count threshold scores. Because CMS has access to Advanced APM participation information and Medicare FFS payment amount and patient count information, MAQI participants would not need to submit Medicare FFS data in this Form.

MAQI participants requesting MIPS waiver determinations would be required to submit this Form during a specified time of the year for the Performance Period. CMS will not review Forms submitted after the Submission Deadline.

B. Justification

1. Need and Legal Basis

Authority for collection of this information is provided under Section 402 of the Social Security Amendments of 1967 (as amended). Section 402(a)(1)(A) authorizes the Secretary of Health and Human Services to develop and engage in "experiments and demonstration projects" to determine whether changes in methods of payment or reimbursement would increase the "efficiency and economy of (Medicare) health services… through the creation of additional incentives …without adversely affecting the quality of such services."

The MIPS requirements that could be waived under this Demonstration are related to payment to clinicians under Part B. Specifically, the MIPS payment consequences are themselves payment provisions applicable to MIPS eligible clinicians pursuant to section 1848(q) of the Act. The reporting requirements that could also be waived for qualifying participants under the Demonstration are related to payment because the MIPS payment adjustments are based on the information and data reported by MIPS eligible clinicians. In CMS' view, this relationship between the reporting and payment adjustments under MIPS means that the MIPS reporting is intrinsically related to payment under Part B for MIPS eligible clinicians.

The MAQI Demonstration may allow participating clinicians the opportunity to qualify for the Demonstration Waiver. CMS would use the authority in section 402(b) to waive section 1848(q)(6) of the Act and the regulations implementing it, to waive the payment consequences and to waive the MIPS reporting requirements in 42 C.F.R. part 414 adopted to implement the payment consequences, subject to conditions outlined in the Demonstration. As a practical matter, the waiver would have the effect of acting as another exclusion from the MIPS reporting requirements and payment adjustment for clinicians who participate in the MAQI demonstration and meet the performance thresholds set in the demonstration. To qualify for the Demonstration Waiver, a participating clinician would be required to participate to a sufficient degree in some combination of Qualifying Payment Arrangements with MAOs and Advanced APMs in FFS Medicare during the performance period for that year. The threshold to qualify for the Demonstration Waiver using participation in these specific payment arrangements could be met in one of two ways: either as a certain percentage of payments or patients. These thresholds would match the thresholds under the Medicare Option of the QPP.

CMS may also waive the requirement that the Secretary to permit all eligible professionals (that is, clinicians) to voluntarily report even if they are not required to do so under MIPS regulations, so that the Demonstration will prohibit reporting under the MIPS by clinicians who participate in the Demonstration and meet the thresholds to receive the waivers from MIPS reporting and payment consequences for a given year. This waiver would be necessary to prevent the potential gaming opportunity wherein clinicians could intentionally report artificially poor performance under the MIPS for years in which they receive waivers from MIPS payment consequences, then receive inflated quality improvement points under MIPS in later years when they do not receive waivers from MIPS payment consequences.

2. Information Users

If the demonstration moves forward, CMS plans to use this data to implement and test the MAQI Demonstration, with its associated research questions. More specifically, CMS would review the information collected in both forms to determine whether clinicians meet the conditions for waivers of MIPS reporting requirements and payment adjustments set forth in the Demonstration and therefore may receive the waiver afforded under the Demonstration. Information collected as part of the Qualifying Payment Arrangement Submission Form would provide a basis for CMS to determine whether a clinician's contractual/payment arrangement is a Qualifying Payment Arrangement under the MAQI Demonstration. For example, the information collected could be reviewed against the Demonstration's standards for minimum financial risk. Information collected as part of the Threshold Data Submission Form would allow CMS to make the calculations necessary to determine whether the MAQI participant meets the threshold(s) required to receive waivers from MIPS reporting requirements and payment adjustments under the Demonstration.

While selection of qualifying clinicians would be the main use of these data, CMS might also use this information to inform monitoring and the evaluation of the MAQI Demonstration as needed and in conjunction with the MAQI Demonstration's research questions.

Finally, this data may be used by the Department of Justice, a court, or adjudicatory body, another federal agency investigating fraud, waste, and abuse, appropriate agencies in the case of a system breach, or the U.S. Department of Homeland Security in the event of a cybersecurity incident.

3. Use of Information Technology

All the information collection described in this form is proposed to be collected electronically. A web-based application tool would house the forms to be used in collecting information/data. The web-based information/data collection tool would adhere to CMS security and privacy rules/regulations.

4. Duplication of Efforts

The proposed information to be collected is not duplicative of similar information collected by the CMS. The final data collection and associated burden for the MAQI Demonstration are specific to the unique parameters under which this project is being operated. If alternate sources for collecting information become available in the future, these situations are described in this package and noted as areas where information will no longer be needed under this review.

5. Small Businesses

Because the vast majority of Medicare providers (well over 90 percent) are small entities within the definition in the Regulatory Flexibility Act (RFA), HHS's normal practice is to assume that all affected clinicians are "small". In this case, most Medicare and Medicaid eligible clinicians are either non-profit entities or meet the Small Business Administration's size standard for small business. We therefore assume that the proposed collection of information will have minimal impact on small businesses or other small entities, since qualifying for the MIPS exclusion under the MAQI demonstration would provide exemption from reporting and other requirements under MIPS.

6. Less Frequent Collection

If data on qualifying arrangement and patient counts/payments are not collected from individual eligible clinicians or groups annually, we would have no mechanism to: (1) determine whether a Demonstration participant's payment arrangement is a Qualifying Payment Arrangement (under the MAQI Demonstration), or (2) assess whether a Demonstration participant's payment amount threshold or the patient count threshold are sufficient for them to receive the exclusion from MIPS (under the MAQI Demonstration).

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published in the Federal Register (84 FR 731) on 1/31/2019. One comment was received from health organization expressing appreciation to CMS for allowing TIN level participation in the application process and suggested additional safeguards to proprietary information. The organization also suggested design changes, however this is outside of the scope of the PRA package. CMS has provided response to the comment in the response to comment document.

The 30-day Federal Register notice published in the Federal Register (FR) on TBD.

9. Payments/Gifts to Respondents

No gift or payment would be provided for providing data as part of the forms referenced in this package.

10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, any confidential information (as such terms are interpreted under the Freedom of Information Act and the Privacy Act of 1974), and will be protected from release by CMS to the extent allowable by law and consistent with 5 U.S.C. § 552a(b).

This information collection is associated with CMS System of Record Notice (SORN) #09-70-0591 (Master Demonstration, Evaluation, and Research Studies for the Office of Research Development and Information (DERS)). The statutory authority for maintenance of this SORN is given under the provisions of § 1110 of the Social Security Act (the Act), which authorizes research and demonstration projects under Social Security Act programs; § 1115 of the Act, which authorizes Medicaid demonstrations; and § 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1), which authorizes waivers of Medicaid and Medicare provisions under certain demonstrations.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

For 2018, CMS estimates that about 100,000 clinicians could respond to the MAQI Demonstration. This number is based on demonstration actuarial and design analyses, which suggested a range of 293,563 (high) to 14,178 (low) clinicians have qualifying arrangements with MAOs. The range of clinicians having Qualifying Payment Arrangements that was developed in our analyses is large because there is very limited data available on the contracts and payment arrangements between MA plans and their network clinicians. Our final estimate of 100,000 clinicians for 2018 is the best estimate of what response to the MAQI Demonstration may look like given the information available.

The total annual estimated cost would be $141,870,000 for the MAQI Demonstration, assuming an

estimated response time for each proposal of 15 hours, a total of 100,000 respondents to the demonstration solicitation, and salaries of the respondents (a Health Service Manager – 47.29/hr.) to be $94.58 per hour – including fringe benefits (https://www.bls.gov/ooh/management/medical-and-health-services-managers.htm). The annual burden hours are estimated to be a total of 1,500,000.

The MAQI Demonstration is requesting review of two forms: a) the Qualifying Payment Arrangement (QPA) Submission Form, and b) the Threshold Data Submission Form. These forms would allow CMS to evaluate whether the payment arrangement that clinicians have with MAOs meet the Qualifying Payment Arrangement criteria, and determine whether a clinician's MAO and FFS APM patient population or payments meet demonstration thresholds. Both of these areas are also requirements for review and data collection under QPP (i.e. the Eligible Clinician-Initiated Other Payer Advanced APM Determination form and All-Payer QP Submission form), and therefore almost identical forms have been prepared and reviewed under the QPP.

Given these similarities in forms, burden estimates for the MAQI Demonstration PRA package were derived from burden analyses and formulation done in conjunction with the QPP forms; more specifically the estimated burden associated with the submission of payment arrangement information for Other Payer Advanced APM Determinations: Eligible Clinician-Initiated Process, and the estimated burden associated with the submission of data for All-Payer QP determinations. Full detail of how these estimates were derived can be found in the forthcoming Calendar Year 2019 Proposed QPP rule.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Because the MAQI Demonstration proposes to test a new set of waivers, exempting clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) (combined with participation, if any, in Advanced Alternative Payment Models (APMs) with Medicare Fee-for-Service (FFS)) from the Merit-based Incentive Payment System (MIPS) reporting requirements and payment adjustments, there would be implementation, program administration and research evaluation costs associated with the project. CMS intends to leverage existing infrastructure (including the QPP programs and systems) to the extent possible. Aside from implementation, program administrative and research evaluation costs, the MAQI Demonstration is anticipated to be budget-neutral and present no cost to the federal government since there are no clinician incentive payments associated with the project.

The total direct salary annual cost to the government for the MAQI demonstration would be $19,762 assuming an estimated 11 senior level CMS staff involved in the review. However, the entire three year cost will be $59,286. Here is the annual cost breakdown:

40hrs. (5 GS. 13); 30hrs (4 GS. 14); and 20hrs. (2 GS. 15) for a total of 360hrs. (i.e., 200hrs, 120hrs, and 40hrs) and a corresponding hourly rate of $49.73; $58.76 and $69.12. Please refer to the OPM Salary Scale (https://www.federalpay.org/gs/locality/washington-dc) and the table below for calculation details.

Government Annual Cost Calculation Table:

Grade/Step	# of Staff	# of Hrs./staff	Total Hrs.	Rate/Hr.	Total Cost
GS 13/3	5	40	200	$49.73	$9,946
GS14/3	4	30	120	$58.76	$7,051
GS15/3	2	20	40	$69.12	$2,765
Total	**11**	**--**	**360**	**--**	**$19,762**

15. Program or Burden Changes

No change in burden anticipated under this program. However, we have made other changes to the information collection request. As stated in Section A.1. of the Background section of this document, we have revised the CY19 submission timeline. We have also made other clarifying edits to the collection instruments and those edits are highlighted in the crosswalk documents submitted with this information collection request.

16. Publication/Tabulation Dates

CMS will be providing feedback to clinicians and third party data submitters already as part of MIPS; therefore data collected under this package will not create new publications, but rather will be incorporated in the information already being reported to the public. The MAQI Demonstration will allow participating clinicians to have the opportunity to be exempt from MIPS reporting requirements and payment adjustments for a given year if they participate to a sufficient degree in Qualifying Payment Arrangements with MAOs (and Advanced APMs with Medicare FFS) during the performance period for that year, without requiring them to be QPs or otherwise meet MIPS exclusion criteria. CMS would ensure that clinicians who meet this exemption are reflected in the already planned reporting accordingly.

In addition, CMS already has plans to publicly report MIPS information through the Physician Compare website; either on public profile pages or via the Downloadable Database housed on www.data.medicare.gov for the purpose of promoting more informed health care choices for people with Medicare. The public reporting is anticipated to start in late 2019 for the 2018 MIPS performance period. We plan public reporting of some measures in a MIPS eligible clinician's MIPS data; in that for each performance period, we will post on a public website (for example,

Physician Compare), in an easily understandable format, information regarding the performance of MIPS eligible clinicians or groups under the MIPS. The Physician Compare performance year 2016 measures will be available for preview at the Physician Compare website https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/

CMS has plans to provide relevant data to other federal and state agencies, Quality Improvement Networks, and parties assisting consumers, for use in administering or conducting federally-funded health benefit programs, payment and claims processes, quality improvement outreach and reviews, and transparency projects.

17. Expiration Date

The expiration date will be displayed on all data collection forms. CMS will also include the expiration date on the following web site https://app1.innovation.cms.gov/MAQICustom which will be available in August 1, 2019 for Eligible Applicants to submit data/information to be considered for MIPS exemption.

18. Certification Statement

There are no exceptions to the certification statement.