AGENCY: Centers for Medicare & Medicaid Services (CMS)

ACTION: Request for Information (RFI)

BACKGROUND:

Program integrity requires that we protect the resources entrusted to our nation's public health care programs while also protecting the health and well-being of beneficiaries. CMS must work every day to guarantee that we are an accountable steward of Medicare and Medicaid program dollars. Accomplishing this is one of CMS' top priorities.

We have historically defined program integrity very simply: "pay it right." Program integrity must focus on paying the right amount, to legitimate providers and suppliers, for covered, reasonable, and necessary services provided to eligible beneficiaries while taking aggressive actions to eliminate fraud and abuse. In recent years, program integrity has proportionally gained a higher profile in the overall management of the Medicare program. Rapid change and growth in Medicare have presented immense challenges and demanded creative solutions from CMS as we strive to "pay it right." Since the Medicare program's inception, the number and types of providers and suppliers have grown exponentially, as have the types of benefits available, the number of claims processed and paid and, perhaps most importantly, the number of dollars involved. All of these changes have raised the stakes for program integrity to historically high levels. Taxpayers have more to lose than ever before from entities and individuals who would, whether intentionally or accidentally, seek improper payment from our programs. With this increasing significance and attention, CMS must continue to adapt in order to respond and meet challenges through its many existing program integrity actions.

Despite these efforts, the design of many of our most important program integrity tools remains rooted in the past – that is in the fee-for-service (FFS) payment system upon which Medicare was first established in 1965. Because of concerns that providers and suppliers would be hesitant to participate in the new program, the initial emphasis was to ensure that the program was developed with the primary goal of simplifying provider and supplier enrollment and paying claims promptly. Timeliness of claims processing was the central measure by which the success of program contractors was measured. The first payment methodologies were based on "usual and customary" charges or cost reimbursement; payments were made in a FFS health care economy that paid for the volume of items and services provided, not necessarily for their quality or appropriateness. While working well in certain respects, the FFS payment system presented a set of built-in incentives that have contributed to fraud, waste and abuse in our programs and did not require high quality outcomes from the care provided.

Since 1965, the Medicare program and our health care system have changed dramatically, and the program integrity challenges we face today don't always look like the ones we could easily recognize in the early days. New provider/supplier types have entered the program, including

hospices, home health agencies, federally qualified health centers and, soon, opioid treatment programs. More challenging cross-ownership issues have also arisen as health care entities have become more complex, with one corporate parent often owning various providers/suppliers and provider/supplier types. Although they represent only a small fraction of all program participants, unscrupulous providers/suppliers have learned how to prey on our programs. They do this through increasingly complex webs of affiliations that allow them to simply appear, then quickly disappear if they come under scrutiny, and then re-appear and reenroll over and over again as "new" entities when, in fact, they are the same bad actors focused on further harming our programs. Today, Medicare managed care plans serve an increasing number of Medicare beneficiaries, presenting an entirely new set of issues for program management in general, and for program integrity in particular. Similarly, new challenges arise everyday around data analysis and systems, provider education, Medicare claim review, provider/supplier enrollment and appropriate provider/supplier network management, all of which compel us to seek guidance and suggestions from stakeholders.

CMS makes use of many program integrity tools. In the Medicare FFS program, for example, CMS contractors may conduct pre-payment and post-payment review (including using Recovery Audit Contractors), implement auto-deny edits, or, for a limited number of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items and potentially other Medicare services in the future, conduct prior authorization. Medicare Advantage plans, Medicare Prescription Drug Plans, TRICARE, Medicaid and private payers conduct prior authorization on a significantly larger percentage and wider array of claims and claim types than Medicare FFS. We believe commercial insurers may also be using other innovative approaches to strengthen program integrity. We believe CMS can learn from the forward-thinking tools utilized by the private sector to improve our program integrity efforts.

Additionally, the Government Accountability Office (GAO) and HHS Office of the Inspector General (OIG) routinely provide insight and guidance to CMS about program vulnerabilities and opportunities to strengthen program safeguards. While CMS regularly concurs with GAO and OIG recommendations, we believe stakeholders may have recommendations for us to better effectuate worthy recommendations. One goal of this RFI is to identify next-generation strategies, tools and technologies that will assist us in anticipating, assessing and acting in real-time upon opportunities and vulnerabilities highlighted by our partner federal agencies rather than "chasing" the recovery of improper payments.

CHALLENGES AND VISION

Provider Enrollment

To protect the integrity of the current system, CMS uses a wide variety of tools and processes aimed at ensuring proper payments. Some of these tools are applied at the front end of our

programs, while others are used later in the payment or post-payment context. For example, through rigorous gatekeeping efforts, CMS works every day to ensure we enroll only legitimate providers and suppliers. CMS manages 2.5 million distinct Medicare provider/supplier enrollments through the Provider Enrollment Chain Ownership System (PECOS), its system of record. In FY 2018, CMS performed approximately 200,000 initial enrollment screenings, 400,000 revalidations, 150,000 deactivations, 2,000 revocations, and 400 enrollment appeals.

New technology could provide improved access to additional data sources and help CMS identify potentially problematic affiliations upon initial screening and through continuous monitoring. One example would be a new tool or technology that would allow easy, seamless access to state and local business ownership and registration information that could improve CMS' line-of-sight to potentially problematic business relationships.

Electronic Health Records and Finding Documentation Requirements

CMS has done much to foster the advent of electronic health records (EHRs) and while that technology is an important and historic first step, we know that EHRs are unable to provide the seamless connectivity of critical patient health information that is needed across all platforms and payers. To address this, we are exploring new ways to secure next-generation capabilities for health care consumers. One new initiative – MyHealthEData – is designed to empower patients by giving them control of their health care data, and allowing it to follow them through their health care journey. For the first time we are moving towards a system in which patients have control of their data and can take it with them from doctor to doctor, or to other health care providers. MyHealthEData will help to break down barriers that prevent patients from having electronic access and provide true control of their own health records from the device or application of their choice. With this innovative initiative, patients will be able to choose the provider that best meets their needs and then give that provider secure access to their data, leading to greater competition and reducing costs.

To push the EHR frontier forward even further, and encourage the rapid expansion of future EHR capabilities, CMS is also exploring the use of artificial intelligence (AI) and/or machine learning (ML) technologies. These tools hold the promise of more expeditious, seamless and accurate review of chart documentation during medical review to ensure that we are paying for what we get and getting what we pay for. In addition to helping modernize our health care system, this technology could also allow CMS to prevent improper payments and, help us move away from the outdated, expensive, and inefficient paradigm of "pay and chase." To do this we need emerging techniques that can help us extend the life of the Medicare Trust Funds and protect the interests of millions of future beneficiaries by eliminating fraud, waste, abuse and misspending.

CMS is also striving toward requirements for a central repository of documentation for all programs and all payers that is easily accessible within the EHR in order to minimize improper payments and reduce provider and supplier burden. A recent key focus of CMS' program

integrity efforts is the development of a prototype Medicare FFS Documentation Requirements Lookup Service (DRLS). The DRLS will allow providers and suppliers to identify Medicare FFS prior authorization and documentation requirements within their EHR or integrated practice management system, reducing provider and supplier burden while simultaneously addressing a leading cause of improper payments – missing or incomplete documentation. We are also working with the DaVinci project, a private-sector initiative led by Health Level 7 (HL7®), a standards development organization focused on accelerating the adoption of HL7® Fast Health Interoperability Resources (FHIR®) as the standard to support and integrate the exchange of value-based care data. We look forward to what these projects can help us achieve in the future.

Data Analytics and Data Systems

CMS currently has robust data analytics and data systems capabilities. The Fraud Prevention System (FPS) analyzes FFS claims using sophisticated algorithms to target investigative resources, generate alerts for suspect claims, target providers or suppliers, and provide information to facilitate and support investigations of the most egregious, suspect, or aberrant activity. CMS uses the FPS information to prevent and address improper payments using a variety of administrative actions, including claim denials, payment suspensions, Medicare enrollment revocations, and law enforcement referrals. During FY 2017, the FPS generated leads for 172 new investigations and augmented information for 244 ongoing investigations. Based on these leads, the Department of Health and Human Services (HHS) took administrative action against 949 providers and suppliers. FPS edits also resulted in \$32.1 million in savings in FY2017.

Additionally, CMS is focusing on prepayment review of claims that have had historically high rates of improper payments. These efforts are aimed at reducing the number and value of improper payments. In FY 2017, CMS revised the methodology for Medicare Part B outpatient and Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) automated and non-automated medical reviews to be consistent with similar methodologies. CMS estimates that MAC automated medical review edits saved \$3.1 billion; MAC non-automated medical review edits saved \$835.9 million. Improper payments prevention of this sort represented 85.6 percent (\$13.2 billion) of total Medicare FY 2017 program integrity savings. The Medicare FFS program improper payment rate fell from 9.51 percent (\$36.21 billion) in FY 2017, to 8.12 percent (\$31.62 billion) in FY 2018. However, despite our success, we need to move beyond current capabilities and into the future, where new strategies, tools and technologies can help us ensure we remain on the cutting edge of data innovation.

We also have a number of disparate and disconnected legacy data systems and repositories. On their own, each of them served or serves its purpose, but the future requires that we be able to join these disparate systems and bring them to bear in the fight against fraud, waste and abuse without creating entirely new data systems. For example, the

productivity and efficiency of systems, such as the FPS, could be enhanced and increased by the implementation of AI. We want to leverage existing private sector tools and technologies to allow legacy systems that contain current or historic data to work together seamlessly and quickly identify and address program integrity needs and opportunities.

Medicare Claim Review

Medicare now processes and pays approximately 4 million FFS claims per day and over 900 million claims annually. To do this properly – to "pay it right" – contractors must determine whether the claim represents the correct charge, for a covered, reasonable, and necessary service, provided to an eligible beneficiary, by a legitimate provider or supplier, and the item or service is properly documented in the patient record. Doing this, while still paying claims quickly, is a complex task. Increasingly, we have turned to computer edits to automatically review claims before they are paid, and to data analytics, by which we can detect patterns of overuse or other improprieties via post-pay review. But among the almost 1 billion claims processed and paid every year, fewer than 3 tenths of 1 percent receive any sort of medical record review. Put another way, 99.7 percent of all FFS Medicare claims are processed and paid within 17 days without any medical review. When they are medically reviewed, which means a human clinician checks the patient medical record to confirm compliance with Medicare FFS documentation rules, CMS sees a 5 to 1 return on investment when comparing cost to recoveries. The CMS level of medical review is less than that of private commercial payers. Private insurers aggressively use tools such as prior authorization to closely monitor whether claims meet payer guidelines, and they apply these tools and practices to as much as five percent of claims, or more than fifteen times what Medicare does. While more reviews by CMS could reduce improper payments, the need for a clinician to personally review patient charts and determine if claims meet payment requirements is very costly. The level of provider burden associated with medical review is also an important consideration. Looking forward, CMS wants to find new and innovative strategies and technologies, perhaps involving AI and/or ML, that are more cost effective and less burdensome to both providers, suppliers and the Medicare program.

Medicare Advantage

Through Medicare Advantage (Medicare Part C), private health plans are providing for an evergrowing population of Medicare beneficiaries with comprehensive, coordinated care. The primary program integrity tool used in Medicare Advantage is contract-level risk adjustment data validation (RADV) audits. This audit process is used to confirm that diagnoses submitted by plans related to the care of Medicare beneficiaries are substantiated within an individual patient's medical record. Performing RADV audits is not only expensive and time-consuming for CMS but also expensive and burdensome on plans and providers/suppliers who must submit voluminous patient records for review. CMS wants to find ways to do more of these important program integrity reviews but at lower cost – to both plans and CMS – and with substantially

less burden on our plan partners and providers/suppliers. Innovative strategies, tools and technologies are vital to achieving these goals.

Value-Based Payment Systems

CMS has implemented a number of value-based payment (VBP) programs and models as part of our strategy to improve how health care is delivered and paid for in the Medicare program. These VBP programs and models include traditional pay-for-performance programs (e.g., the Merit-Based Incentive Payment System, Hospital Value-based Purchasing Program) and new payment models (e.g., Accountable Care Organizations, Bundled Payments). Congress created the CMS Center for Medicare and Medicaid Innovation (Innovation Center) in 2010 to test new approaches or "models" for paying for and delivering health care services. Together, CMS' payfor-performance programs and the Innovation Center's new payment models aim to align FFS Medicare payments for providers and suppliers with health outcomes, rather than the volume of services provided.

Under pay-for-performance programs, providers and suppliers may be rewarded or penalized for satisfying specified quality measure reporting requirements. CMS implemented VBP programs as a way to improve the quality of care provided to Medicare beneficiaries.

CMS is testing a diverse set of models. Under the Innovation Center's bundled payment models, for example, participating providers and suppliers can often take accountability for the cost and quality outcomes for a specific clinical episode of care. Under these bundled arrangements, participating providers and suppliers can take accountability for patients over a defined period of time that typically begins with an acute event, such as a surgical intervention, and extends after discharge. In most cases, these models rely on the traditional FFS payment system with a retrospective reconciliation process.

The Innovation Center also has models in which participants are taking accountability for patient care over a longer period, such as a year. The design of some of these models, for example, the Next Generation Accountable Care Organization (ACO) model, and the recently announced CMS Primary Care Initiative, moves away from the traditional FFS payment system. The design of these models and the accountability for cost and quality outcomes in particular reduces the incentive to provide unnecessary services in order to maximize payments. Since these models mitigate the incentive to provide unnecessary services to maximize payment, existing medical review protocols aimed at identifying overutilization may need to be modified or re-engineered. CMS is interested in ideas from industry regarding how program integrity, and more specifically medical record review, should be applied to VBP initiatives..

However, concerns about potential improper payments and bad actors remain. Under both traditional pay for performance programs and new payment models, provider and supplier calculated and reported data on quality of care, as well as information on risk adjustment can

replace FFS coding as critical factors that impact total payment amounts. While concerns about overutilization may diminish, new payment models may raise new concerns regarding underuse, also known as "stinting." In addition, as CMS moves towards more capitated and bundled payments, it may require new approaches to conduct program integrity activities – such as data to evaluate coverage and the appropriateness of care, and monitor other factors, such as beneficiary attribution.

Given that similar VBP programs are being used in the private sector, we are requesting information regarding potential new approaches to address these concerns. This may include the use of advanced analytics, the reporting of alternative (e.g. non claims-based) data, or other mechanisms to identify improper payments, beneficiary safety issues, and other program integrity related concerns. The questions below are designed to capture broad input regarding the design of our VBP programs and any necessary changes warranted to enable improved identification of improper payments.

The emergence of new value-based programs and models also raises real and important questions about ensuring data integrity. Given that VBP programs and models link payment to the quality of clinical outcomes, we must be confident that reported data is accurate, complete, and reliable. Challenges in this area include reviewing and confirming the accuracy, and completeness of both quality data and the data reporting systems used to convey it. We need to determine whether innovative new strategies, tools, and technologies presently exist that can increase data accuracy and integrity and consequently reduce improper payments.

Education

Often, improper payments occur because providers and suppliers have not followed Medicare payment, coverage, and coding guidelines or have not submitted the appropriate requested documentation. Provider/supplier error is often made with no intent to defraud Medicare or misuse its resources.

CMS recognizes the importance of its role in educating providers and suppliers about Medicare's requirements. In addition to continuing our national education efforts such as hosting Open Door Forums and publishing Medicare Learning Network educational materials, we recently began focusing more on personalized education through a process called Targeted Probe and Educate (TPE), conducted by the MACs. TPE involves significant one-on-one education for providers and suppliers. MACs focus only on providers/suppliers who have the highest claim denial rates or who have billing practices that diverge significantly from their peers. TPE involves up to three rounds of one-on-one reviews of 20-40 claims per provider/supplier, per item or service. After each round, providers/suppliers are offered individualized education based on the results of their reviews.

Since the TPE program's inception in late 2017, MACs have made more than 4,300 "round one" educational contacts with providers and suppliers per month. This personalized education is invaluable in helping CMS, providers, and suppliers evolve beyond the "pay and chase" paradigm, moving instead to one where we prevent improper payments before they are made. Preliminary data suggests that TPE has been effective in improving compliance and reducing appeals. Despite our successes, we are limited by a number of factors, including the fact that a significant percentage of providers and suppliers do not respond timely to the opportunity for TPE. We also see opportunities for CMS to better connect ordering physicians and rendering providers/suppliers with respect to their shared responsibility for proper documentation. We also see opportunities for providers and suppliers to become more aware of the necessary documentation requirements earlier in the claim process. It is our hope that by appealing to the private sector and the larger provider community we can determine whether new strategies, tools or technologies exist that we are not currently using to address and resolve these challenges.

GOALS

CMS has a singular purpose – to put patients first. This means safeguarding federal resources, protecting the health and well-being of the 60 million Medicare beneficiaries we are so honored to serve, and working every day to guarantee that our provider/supplier partners – without whom we could not discharge our program responsibilities – are not excessively or unnecessarily burdened by arcane rules and regulations. To do this, we have to make use of all available resources and doing that includes recognizing that sometimes you need a little help. We must look to the best that the private sector, the provider community, and other external stakeholders have to offer in all of these critical areas – whether innovative strategies or new and advanced tools and technologies – and incorporate them into our programs, including Medicaid, wherever possible. Our goal is to bring cutting-edge innovation to all of the areas addressed here and beyond. We want to make sure that our tools not only remain effective in the existing FFS world, but also adapt, grow, innovate and expand to emerging new VBP systems as well. We need to answer the question "what does program integrity look like in a value-based world?"

CMS must elevate program integrity, unleash the power of modern private sector innovation, prevent rather than chase fraud waste and abuse through smart, pro-active measures, and unburden our provider/supplier partners so they can do what they do best – put patients first. For these very important reasons, we seek and welcome input and expertise from all stakeholders on how best to improve our program integrity strategy and tools as we strive to protect both taxpayer dollars and the health and well-being of program beneficiaries.

SUMMARY: CMS is using this RFI to obtain input from stakeholders and experts on innovative methods and tools to elevate the agency's program integrity efforts. CMS will use the feedback

to better align its program integrity initiatives with the changing health care environment and adopt new and innovative technology. While this RFI requests specific input on prior authorization, provider education and program integrity for VBP programs, we are looking for any methods, tools or ideas applicable to our strategy outlined above.

This RFI is organized as follows:

- 1. Program Integrity for Value-Based Payment Programs
- 2. Medicare Advantage
- 3. Prior Authorization in Medicare FFS
- 4. Provider Education

DATES: To be assured consideration, comments must be received by November 20, 2019.

ADDRESSES: Comments should be submitted electronically to:

<u>ProgramIntegrityRFI@cms.hhs.gov.</u> Commenters are encouraged to provide the name of their organization and a contact person, mailing address, email address, and phone number. However, this information is not required as a condition of CMS's full consideration of your comment. Commenters are encouraged to submit their comments in PDF format.

ADDITIONAL INFORMATION: For an opportunity to share your ideas directly with CMS leadership, attend one of our Program Integrity Listening Sessions we're holding across the country. For more information, visit: https://cpievents.cvent.com/d/cygwqr/

Please read the Special Note to Respondents and Collection of Information sections at the end of this document before submitting comments.

1. Program Integrity for Value-Based Payment Programs

Questions on Program Integrity for Value Based Payment Programs

CMS seeks feedback on program integrity in a VBP environment. Specifically:

- 1. What type of opportunities for fraud, waste, and abuse do VBP arrangements present that are similar to or are different from FFS or managed care?
 - a. What specific changes should CMS consider as part of its program integrity strategy to fight fraud, waste and abuse related to the VBP programs?
 - b. Are there lessons from payments to managed care plans under the Medicare Advantage program that CMS can adopt in monitoring capitated and bundled payment arrangements under FFS?
 - c. What lessons can CMS learn from program integrity, beneficiary safety and other factors under the sub-capitated arrangements of private plans in their commercial, Medicaid and Medicare lines of business?

- 2. CMS recognizes that medical review of claims may change under the VBP approach to payment.
 - a. What useful improper payment detection or prevention controls have private sector payers employed to protect against improper payments in a value-based environment? What are the pros and cons of different approaches?
- 3. How can payers ensure that payments in VBP programs accomplish the goals of improving the value of the care provided?
- 4. Do any tools (that are different from CMS' current <u>FPS</u>¹) currently exist with the demonstrated ability to target claims prior to payment that contain improper payments?
- 5. What additional data should CMS collect or examine to evaluate coverage, appropriateness of care, and beneficiary assignment?

2. Medicare Advantage

Questions on Medicare Advantage

CMS seeks feedback on program integrity in Medicare Advantage. Specifically:

- 6. What specific changes should CMS consider as part of its program integrity strategy to fight fraud, waste and abuse related to the Medicare Advantage program?
- 7. Are there lessons from program integrity programs implemented by managed care plans under the Medicare Advantage program that CMS should consider?
 - a. Are there lessons from monitoring of network providers by managed care plans in their commercial business that CMS should consider for payments to managed care plans under the Medicare Advantage program?
- 8. What lessons can CMS learn from the program integrity and other factors under the arrangements of private plans in their commercial, Medicaid and Medicare lines of business?

3. Prior Authorization in Medicare FFS

Questions on Prior Authorization in Medicare FFS

CMS seeks feedback on the potential for prior authorization to be improved. Specifically:

- 9. What program integrity activities should CMS consider to ensure that items or services are provided as approved through the prior authorization process?
- 10. Can clinical decision support tools play a role in prior authorization? If yes, how?
- 11. How can we apply prior authorization without adding to provider and supplier burden?

 $^{^{1}\} https://www.cms.gov/About-CMS/Components/CPI/Downloads/FY-2017-Medicare-and-Medicaid-Integrity-Programs-Report-to-Congress.pdf$

- 12. How can we apply prior authorization while maintaining timely and complete access to medically reasonable and necessary covered services for our beneficiaries?
- 13. While prior authorization helps ensure that services or items to be furnished comply with all applicable coverage and coding rules at the time of the prior authorization request, some requirements cannot be assessed until after care delivery. What information cannot be captured by a prior authorization process? Does this limit or restrict prior authorization?
- 14. Are there other issues with respect to prior authorization that CMS should consider?

4. Provider Education

Questions on Provider Education

CMS seeks feedback on provider education. Specifically:

- 15. What strategies, tools, or technologies exist to help CMS better connect ordering physicians, rendering providers, and suppliers with respect to their responsibility to provide proper documentation?
- 16. What strategies, tools, or technologies exist to help providers and suppliers become more aware of the necessary documentation requirements earlier in the claim process?

SPECIAL NOTE TO RESPONDENTS:

THIS IS A REQUEST FOR INFORMATION (RFI) ONLY. CMS is looking for innovative, but fiscally prudent and operationally feasible, ways to conduct program integrity more effectively and efficiently. We welcome your suggestions for methods to improve oversight of Medicare payments with available technologies. The suggested approaches should consider the effectiveness in fighting fraud, waste and abuse and also the associated burden for providers, suppliers and patients.

We are seeking new ideas that CMS has not previously explored. CMS previously researched technologies for biometrics and smart cards. In addition, we are currently using the FPS with success. We would like to target only tested and proven solutions, not hypothetical ideas. Commenters are encouraged to submit evidence with their ideas. CMS would like to request that submissions be limited to ten pages or less to ensure comments can be reviewed timely and thoroughly.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Respondents are advised that the Government will not pay for any information or administrative costs incurred

in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, should one be conducted. CMS does not anticipate additional notifications regarding the RFI; however, potential respondents should continue to monitor CMS announcements for additional information pertaining to this RFI.

Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not choose to contact individual respondents. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which payment would be required or sought. All submissions become Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

COLLECTION OF INFORMATION REQUIREMENTS:

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. However, this document does contain a general solicitation of comments in the form of a request for information. In accordance with implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the Federal Register or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).