November 15, 2022

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
200 Independence Avenue S.W.
 Washington, D.C., 20201

Re:	Request for Information; Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals (File No. CMS-9900-NC)

Dear Administrator Brooks-LaSure,

The American Psychiatric Association (APA), the national medical specialty society representing over 37,000 psychiatric physicians and their patients, appreciates the opportunity to provide these comments on CMS-9900-NC, Request for Information; Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals. Our January letter[1] written with eleven other behavioral health professional associations, stated our initial concerns about the good faith estimate (GFE)/advanced explanation of benefits (AEOB) system. This response expands upon those concerns, while also responding to specific inquiries in the RFI that are most relevant to psychiatrists. We appreciate that cost transparency empowers patients to make informed healthcare decisions. However, we urge CMS to create standards for this GFE/AEOB process that do not impose undue administrative burdens on clinicians or foster plans' arbitrary limitations on care. We have reviewed the comments from the American Psychological Association and the National Association of Social Workers regarding the RFI and agree with them on many of the same issues.

Accordingly, we ask that CMS provide for:

1. **An exemption for clinicians who provide services for patients with mental and health and substance use disorder (MH/SUD) conditions from the No Surprises Act's (NSA) requirements for furnishing GFEs to insurers for patients who intend to use their insurance.** Psychiatrists are rarely, if ever, the cause of surprise bills that were the focus of the NSA. Services provided

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[1] Letter to HHS Secretary Xavier Becerra, et. al. (January 25, 2022), https://www.psychiatry.org/getattachment/9c785c2b-abcb-45dd-8715-465ce0f19678/APA-Group-Letter-CMS-No-Surprise-Act-Interim-Rules-01252022.pdf

to people with MH/SUD often do not include services from ancillary clinicians that are separate from the primary physician, such as anesthesiologists and assistant surgeons. For patients who are using their out of network benefits, the plans must bear primary responsibility for collecting information about patients' costs and clinicians should only need to drop in their fees and proposed treatment plan.

2. **An exemption for solo, small group and safety net practices providing MH/SUD services from the interoperability requirements**. The establishment of complex and interoperable data systems requires financial, technological, and human capital that would pose a risk to the delivery of patient care in small and safety net practices, and will make access to care that much harder.

3. **A secure, cloud-based clinician portal for electronic submission, storage and retrieval of GFE and AEOB data.** If CMS cannot or will not develop a single portal, then plans should be required to use identical portals that include uniform GFE forms across all plans.

The GFE/AEOB requirements pose unique concerns to psychiatrists, some of whom provide one-to-one care for their patients in their offices without other staff to assist with billing or other administrative duties or use of technology because of privacy concerns. Many psychiatrists have opted out of participating in insurance panels because of existing administrative burdens. We are concerned that the additional administrative burden from AEOB/GFE requirements will push others to leave insurance panels. Our members are reporting that filling out the GFE for uninsured or self-pay individuals and updating it every time there is a minor change in the treatment plan that may or may not have an impact on costs takes away from valuable treatment time – which is in extremely high demand as more and more people are struggling with the mental health impact of the COVID-19 pandemic. Clinicians who are in larger practices with support staff are reporting they are unable to hire additional staff needed to create the GFEs, each taking up to 30 minutes to prepare. Expanding the requirements to insured patients and adding additional technological and infrastructural requirements pose additional challenges to care delivery, including time and resources required to: implement new technologies and workflows; train and troubleshoot processes with staff; maintain the technology, including licensing fees, updates, and compatibility with other existing and emerging technology; and use the technology in each clinical encounter, regardless of the usefulness to that patient at that time. The benefits accrued for this increase in burden are unclear, particularly when, as is being reported, GFE notifications are insufficiently nuanced and incomprehensible to laypeople to aid in patient decision-making.

The technical infrastructure necessary for clinicians and facilities to seamlessly and instantly transmit information to plans across the market does not currently exist, nor do adequate standards for data transfer between clinicians and facilities and plans. Physician practices see patients that are covered by multiple health plans, and the interface between all of them and the physicians does not exist. Once the standards for these data are established across clinical settings and payer environments, technical infrastructure and platforms will need to be built,

readily available, and extensively tested to ensure usability and privacy. After this point, a pilot/hold harmless period will be necessary to test the practice, payer, and patient experience and ensure the technology is accessible, accurate, NSA-compliant, and secure.

Considering the urgent workforce and capacity shortages facing health care delivery, particularly acute in MH/SUD care, it must be the responsibility of the plans to ensure that this interface exists between itself and its network. It also must be the plans' responsibility to provide information related to patients' deductibles and benefits, and the clinicians' reimbursement rates. These burdens should not be added to the clinicians who are trying to care for patients, and plans are significantly better-suited to design and deploy enterprise-level technology solutions than individual practices.

There will also be unintended consequences such as driving out clinicians and providing highly vulnerable patients with unhelpful and confusing information that could encourage care avoidance in a population coping with MH/SUD challenges, stigma, and stress. In addition, we are also concerned that plans could use the information contained in the GFE/AEOBs to limit patient care by issuing medical necessity denials. Benefits to patients are minimal considering the potential for this effort to confuse and scare patients and reduce overall access to care, introducing inequitable impacts that disproportionately negatively affect patients with low incomes and low health or financial literacy and to clinicians that practice in small, rural, and/or safety-net settings.

APA strongly encourages CMS to use normal rule making processes to roll out these regulations, instead of issuing a final interim rule, given the complexities involved. APA also strongly encourages CMS to continue to exercise discretion in enforcement of the GFE requirements.

APA's responses to the Departments' questions, most relevant to our members and the patients they care for, are as follows:

- **What issues should the Departments and OPM consider as they weigh policies to encourage the use of a FHIR-based API for the real-time exchange of AEOB and GFE data?**

Using FHIR based APIs for exchanging AEOB and GFE data will require time, money, technical expertise and additional staff to support continual updating and testing. FHIR is not a "plug and play" solution but a starting point. Information going into the FHIR-based real-time exchange must be in a properly structured electronic format and include key data elements, such as identifying information from each plan, information on the different contracts/carveouts and coverage provided by each insurance plan, information on patient's primary and secondary insurance and patient specific identifiers, among many other data elements. The system will also have to integrate information coming in from numerous sources.

APA strongly encourages the Departments to consider that clinicians already have high levels of administrative burden, which contributes to physician burnout and reduces access to care. We are concerned that adding requirements around the use of FHIR-based APIs for exchanging AEOB and GFE data will add to this burden for all clinicians and especially solo and small practices, many of which lack of Electronic Health Records (EHRs) and other electronic data management and administrative/billing/reporting support. Medical facilities have not recovered their financial health from the COVID-19 pandemic, and many are not hiring additional staff including information technology personnel that will be critical to keeping such an exchange up to date.

- **What privacy concerns does the transfer of AEOB and GFE data raise, considering these transfers would list the individual's scheduled (or requested) item or service, including the expected billing and diagnostic codes for that item or service? Does the exchange of AEOB and GFE data create new or unique privacy concerns for individuals enrolled in a plan or coverage? Are there any special considerations that Departments should take into account regarding individuals who are enrolled in a plan or coverage along with other members of their household? How should the Departments and OPM address these concerns?**

The APA strongly urges CMS to consider methods to prevent payers from misusing data captured during AEOB and GFE interactions. Moreover, CMS should initiate policies that explicitly prevent payers from using AEOB and GFE data for anything other than the provision of advanced estimates and require internal firewalls between systems and teams involved with GFE/AEOB data and all other arms of the health plan, such as network maintenance, utilization management, and coverage policies. Without such safeguards, any transparency gains may come at the price of patient privacy and data security, as well as access to medically necessary care. In situations where an individual is enrolled in a plan or coverage along with other members of their household, APA is concerned about the possibility that private information could be inadvertently disclosed to other members of the household.

APA is also concerned that requiring the creation of GFE/AEOBs, while a laudable goal to help inform patient decision making, increases the risk of a data breach, particularly if each plan uses a different platform for submitting information. APA recommends the creation of a single secure, cloud-based clinician portal for electronic submission, storage and retrieval of GFE and AEOB data.

- **How could updates to this program support the ability of clinicians and facilities to exchange GFE information with plans, issuers, and carriers or support alignment between the exchange of GFE information and the other processes clinicians and facilities may engage in involving the exchange of clinical and administrative data, such as electronic prior authorization?**

Exchanges of clinical and administrative data continue to pose a considerable administrative burden to our members. Such requirements, including those for prior authorizations, have grown

exponentially. As a result, psychiatrists spend an inordinate amount of time on uncompensated tasks, leaving far less time for treating patients. Members report routinely having to use a fax machine to submit or receive prior authorization information, even though fax machines have been outmoded for years in other businesses. Other challenges when securing prior approval for a patient's medication, include needing to contact the pharmacy for information about insurance refusals for prescriptions, receiving incorrect phone numbers for seeking approval, waiting on hold for up to an hour when trying to get approvals, and spending significant time and effort, as often as every 3-6 months, renewing longstanding medications that are needed to prevent relapse or hospitalization.

Accordingly, while an electronic system that "bundles" several digital communications between payers and practices (and, ideally, patients) would be ideal to reduce the administrative burden on clinicians so that they can spend their time caring for patients, this solution would need to be carefully, thoughtfully designed with the end-users (including psychiatrists) in the room. Rather than relying on private technology platforms that over-promise and under-deliver; government entities can help translate between practice needs and technological capabilities

- **Would the availability of certification criteria under the ONC Health IT Certification Program for use by plans, issuers, and carriers, or health IT developers serving plans, issuers, and carriers, help to enable interoperability of API technology adopted by these entities?**

Not necessarily. Certification criteria under the ONC Health IT Certification Program are primarily aimed at general functionality (e.g., the system must include e-prescribing). For many use cases that require complex data exchange, data fields and structures are insufficiently standardized to a degree that would enable API-driven interoperability. Additionally, many of the behavioral health-specific products are not ONC-certified, and several vendors of these products have already gone out of business, demonstrating significant challenges with technological "churn" that increases the burden and reduces the effectiveness of uptake of new technologies. Even if there is a separate module available for MH/SUD, clinicians/facilities may be limited in their ability to purchase it or upgrade due to cost, lack of staff time and resources and historically low reimbursement rates. Having some standardization of what would need to be built into the systems would be helpful, but this would also require lag time for upgrades and functionality.

- **What, if any, burdens or barriers would be encountered by small, rural, or other clinicians, facilities, plans, issuers, and carriers in complying with industry-wide standards-based API technology requirements for the exchange of AEOB and GFE data? How many small, rural, or other clinicians, facilities, plans, issuers, and carriers would encounter these burdens or barriers in complying with such technology requirements?**

Most small/rural practices serving the medically underserved would struggle with complying with these technology requirements.   Accordingly, without infrastructural, implementation, and

workflow support accompanying this requirement, it runs the risk of entrenching existing systemic barriers and inequities in these communities, especially if noncompliant practices are penalized. Patients in rural communities may also be less likely to have access to reliable internet access, which could affect their ability to use patient portals or other means of receiving electronic communications about AEOB. Further, patients belonging to historically excluded groups and patients with low incomes may be disproportionately at risk of care avoidance due to potentially inaccurate GFEs. Potential equity impacts of this effort should be closely tracked and mitigated where possible.

- **Are there any approaches that the Departments and OPM should consider, or flexibility that should be provided (such as an exception or a phased-in approach to requiring clinicians and payers to adopt a standards-based API to exchange AEOB and GFE data), to account for small, rural, or other clinicians, facilities, plans, issuers, and carriers?**

APA recommends the Departments provide exceptions, like the exceptions to meeting Merit-based Incentive Payment System (MIPS) program requirements, f**or adopting a standards-based API to exchange AEOB and GFE data to clinicians. Such exceptions could include:**

- extreme and uncontrollable hardship that is outside the control of the clinician, such as disaster, practice closure, severe financial distress or vendor issues;
- undue hardship, such as having decertified EHR technology; insufficient Internet connectivity; or solo/small sized practice that fall below a certain staffing level or patient volume;
- any data related to an initial visit with a patient, where a patient is shopping for care/interviewing the clinician to determine if they are the right match for them; and
- when insured patients are incorporated into the rule, where inadequate information is available from plans to make an accurate determination of patient liability (e.g., PAR determination not received, primary/secondary coverage determinations not available). See, https://qpp.cms.gov/mips/exception-applications

When interoperability requirements are put into effect, a phased-in approach will be necessary to ensure adequate time for identification, implementation, and adoption of new technology as well as workforce expansion, training, and workflow modifications.

- **If the Departments and OPM were to provide such flexibility, what factors should they consider in defining eligible clinicians, facilities, plans, issuers, and carriers?**

Solo/small practices often use low-tech or manual billing systems. The time and cost for these clinicians to convert their systems will divert clinician time away from patient care, may be cost-prohibitive, particularly in view of low reimbursement rates for psychiatric care, and may drive many out of business, further shrinking access to care.

- **Generally, how should the AEOB reflect the way in which the No Surprises Act's or a State's surprise billing and cost-sharing protections may affect an individual's benefits related to the items or services specified in an AEOB, and the individual's financial responsibility for these items or services?**

If an AEOB is to reflect the way the NSA or a state's surprise billing and cost-sharing protections affects an individual's benefits related to the items or services in the AEOB, it must be the plans' responsibility to collect and provide this information.

All communications should be delivered in the patient's primary language and concordant with the patient's health and financial literacy.

Impact to the patient's deductible and out of pocket costs should be explicitly stated, along with an explanation of what these items each mean (e.g., "The price of the service is $1200. Your deductible is $1000, which is the amount you must pay every year before your insurance starts paying. You will pay $1000 for this service and your insurance company will pay $200").

Live (chat, phone) support should be available to each patient from their plan to comprehend and apply AEOB/GFE information to decision-making. Quality checks and metrics on these support lines should be mandatory with clear and reasonable benchmarks. Patients should not have to sit on infinite hold to get a response and clinicians should not be using clinical time to explain the AEOBs to patients.

- **In instances in which the plan, issuer, or carrier, at the time it is preparing the AEOB, has knowledge that the No Surprises Act's or a State's surprise billing and cost-sharing protections would apply unless individual consent has been given, but the plan, issuer, or carrier does not know whether consent has been given by the individual to waive those protections, should the AEOB include two sets of cost and benefit data, one set that would apply if consent is given, and one set that would apply if consent is not given?**

Patient circumstances should be reflected in the implementation of these requirements to the greatest extent possible, so requiring plans to provide both with-consent and without-consent scenarios may be valuable.

- **To what extent could the Departments' and OPM's coordination of the internet-based self-service tool requirements with AEOB requirements help minimize the burden on plans, issuers, and carriers in implementing both requirements?**

APA is uncertain what these would consist of. If these requirements were meant for clinicians to use for data entry in lieu of APIs, they could make matters worse, particularly if they were mandated but were poorly designed/slow/erratic/etc. It is the health plan that is selling coverage of a clinical service; as such it has most of the information required to provide an estimate. This should not rest with the clinician who is being paid to provide clinical care.

- **Can plans, issuers, and carriers leverage technical work done to comply with the internet-based self-service tool requirements to help streamline the process for complying with AEOB requirements?**

If specifications and criteria for web-based tools are readily accessible, relevant entities may be able to leverage these components to improve compliance.

- **What, if any, obstacles would be encountered if plans, issuers, and carriers were required to provide AEOBs to covered individuals for all covered items or services (rather than a specified subset, similar to the rule for the first year of the internet-based self-service tool requirement) beginning with the first year of implementation of the AEOB provisions?**
- **Are there reasons why the Departments and OPM should or should not propose a requirement that plans, issuers, and carriers provide a copy of the AEOB to the clinician or facility, as opposed to allowing such a transfer but not requiring it?**

APA urges CMS to require that health plans provide a copy of the AEOB to all clinicians and facilities that have submitted GFEs for a patient's scheduled treatment. It is in the best interest of the patient that the clinician/facility has the same record of cost and coverage information the patient has received to facilitate informed conversations regarding care costs.

- **What, if any, burdens or barriers should be considered if the Departments and OPM propose to require plans, issuers, and carriers to communicate a covered individual's request for an AEOB to a particular clinician or facility in order to receive GFE information from the clinician or facility for use in formulating the requested AEOB?**

If secure electronic communication is not feasible, clinicians should be held harmless to ensure ongoing ability to provide care to patients.

- **What approaches should be considered when proposing requirements related to the AEOB and GFE that account for, or do not account for, secondary and tertiary payers?**

Currently, when a patient has multiple forms of health coverage it can be difficult to determine coverage. Requirements related to transferring data needed for the AEOB/GFE need to consider the sequential nature of these determinations with primary coverage needing to be established before subsequent coverage can be pursued. Currently, this coverage coordination is done via many phone calls and involves a heavy administrative burden for clinicians/facilities. Accurate and timely AEOB/GFE may not be available until the conclusion of this complex, manual coordination process, and inaccurate GFEs can pose significant risk to equity and outcomes.

- **The Departments and OPM are interested in plans', issuers', and carriers' perspectives on whether a diagnosis code would be required for the calculation of the AEOB. Are there items or services for which a plan, issuer, or carrier would not be able to determine points of information such as: (1) the contracted rate; (2) the coverage level (that is, if the plan or issuer covers an item or service associated with one diagnosis at a higher rate than an item or service associated with another); or (3) whether an item or service is covered (that is, if the item or service is covered for one diagnosis but not another) for an item or service based on the service code and other information in the GFE in the absence of a diagnosis code?**

It often takes time for clinicians to establish a diagnosis, and more than one visit can be needed to fully identify the patient's diagnosis and treatment needs.   Further, the process of creating an AEOB should not be one that allows a plan to eliminate care. Engaging patients in care is already a challenge due to stigma and access. APA remains concerned that providing patients with a total dollar amount of a full year of treatment could cause some patients to have "sticker shock" and opt to not even start treatment.   All these scenarios pose the risk of negatively impacting clinical care and confusing patients with inaccurate/incomplete information in the AEOB/GFE.

- **What, if any, additional burden would be created by requiring clinicians, facilities, plans, issuers, and carriers to conduct (1) verification to determine whether an individual is uninsured, self-pay, or enrolled in a health plan or coverage for AEOB and GFE purposes; (2) verification of coverage for each item or service expected to be included in an AEOB or GFE; or (3) verification of coverage from multiple payers? Do clinicians and facilities already perform these types of verifications in the regular course of business, such that minimal additional burden would be imposed?**
- **Would it alleviate burden to allow clinicians and facilities, for purposes of verifying coverage, to rely on an individual's representation regarding whether the individual is enrolled in a health plan or coverage and seeking to have a claim for the items or services submitted to the plan or coverage? What might be the implications of taking this approach?**

APA recommends the Departments allow clinicians and facilities to rely on an individual's representation regarding whether the individual is enrolled in a health plan. Clinicians/facilities already ask for patients to provide their insurance card, and this is a reasonable and good faith effort to verify a patient's coverage. In cases where a patient changes jobs and is no longer covered by insurance, the plans are in a better place than the clinicians to figure out a patient's coverage. This, however, raises questions about how the interoperable data system will know about and react to insurance updates, job changes, and open enrollments, for example.   Going forward there will need to be improvement in the interoperability of payer data systems, and plans should drive this structural change to improve information flow between plan, clinician, and patient.

- **What unique barriers and challenges do underserved and marginalized communities face in understanding and accessing health care that the Departments and OPM should account for in implementing the AEOB and GFE requirements for covered individuals?**
- **What steps should the Departments and OPM consider to help ensure that all covered individuals, particularly those from underserved and marginalized communities, are aware of the opportunity to request AEOBs and GFEs and are able to utilize the information they receive in order to facilitate meaningful decision-making regarding their health care?**
- **Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A-1(f) and 2799B-6 require the AEOB and GFE to be provided in clear and understandable language. What additional approaches should be considered that would facilitate the provision of AEOBs and GFEs that are accessible, linguistically tailored, and at an appropriate literacy level for covered individuals, particularly those from underserved and marginalized communities and those with disabilities or limited English proficiency? Is there any specific language or phrasing that should be used to help mitigate any potential consumer confusion?**

AEOB and GFE requirements need to account for linguistic, financial, and health literacy in communicating about care and the costs of treatment with patients. This is crucial to avoid unintended consequences of care avoidance, financial burden, and stress among patients with mental health needs. These considerations include:
  - Clearly stating the patient's financial responsibility
  - Clearly stating any assumptions, uncertainties, limitations, or pending components of the AEOB/GFE
  - Providing live, multilingual support to any patients with questions about their financial liability
  - Being clear that the AEOB/GFE is not a bill
  - Recognizing that patients who work seasonal or "gig" jobs, work unpredictable hours, or experience other sources of financial and social disruption may frequently change ("churn") insurance sources and that GFEs may be inaccurate if the patient's payer or coverage status changes
  - Recognizing that patients with challenges accessing care that may include lack of access to transportation or childcare coverage, lack of broadband or cell coverage, linguistic or cultural barriers, and other health-related social needs considerations do not have the time or resources to reconcile inaccuracies in the AEOB/GFE and may be subject to unnecessary financial stress, care avoidance, and other negative outcomes.

- **Should the Departments and OPM consider adopting AEOB language access requirements that are similar to the Departments' existing requirements for group health plans and health insurance issuers, such as the internal claims and appeals and external review and Summary of Benefits and Coverage (SBC) requirements to provide oral language services, notices in non-English languages, and non-English language**

statements in English versions of notices indicating how to access language services? If so, what is the best way to ensure that information about language access services is communicated far enough in advance to facilitate the provision of the AEOB in the language that is most accessible to the individual?

Yes. Consistency among different requirements is important to reducing confusion among clinicians about requirements. Having appropriate language information is critical for patients.

- **Specifically, the Departments and OPM are interested in estimates of the time and cost burdens on clinicians and facilities, and separately on plans, issuers, and carriers, for building and maintaining a standards-based API for the real-time exchange of AEOB and GFE data. What would be the costs for purchasing and implementing a standards-based API for the real-time exchange of AEOB and GFE data from a third-party vendor, compared to building standards-based API functionality in-house? What percent of clinicians, facilities, plans, issuers, and carriers are likely to either purchase and implement the API via a third-party vendor compared to building and implementing the API in-house? How do these costs compare to alternative methods of exchanging AEOB and GFE data, such as through an internet portal or by fax?**

A precise estimate of the time and cost burdens on clinicians and facilities would depend on the ultimate requirements for real-time exchange of AEOB and GFE data. Nevertheless, we expect these costs, including those for personnel, will be considerable. Many times, with IT initiatives, the focus tends to be on upfront costs and not maintenance costs. However, the ongoing maintenance costs often end up being significantly more costly because systems are constantly being upgraded and it takes multiple people to do the upgrade and then test it across multiple systems. Some facilities or large groups of clinicians may have sufficient IT capabilities to build and maintain a standards-based API "in house". Time would still be needed to build all of the required data elements in the system and then construct the relevant interfaces. Standardization of the required data elements and minimization of the number of distinct interfaces would be crucial to doing this in an efficient manner.

As an alternative to "in house" building and maintaining of an API, a third-party vendor could provide these services, but use of a third-party vendor does not eliminate the need for staff time in connecting the third-party product to the local information system(s) or standardizing information that is captured in the local system(s). Third party products can be expensive, are often "niche" products, developed by technology "startups" that do not always deliver on stated features, and can leave the marketplace precipitously without support for purchasers. In addition, without a certification process for third party vendors, standardization efforts could become more complicated and more challenging.

While we appreciate that the original intent of the No Surprises Act was to protect patients from surprise billing, most of which occurs outside the mental health space, we are concerned that an

unintended consequence of implementing such a large-scale effort could have a detrimental impact on overall access to MH/SUD care. **We strongly encourage the administration to be thoughtful and measured in its approach as it moves forward.** Thank you for your consideration of our response. If you have additional questions, please direct them to Maureen Maguire at MMaguire@psych.org.

Sincerely,

Saul M. Levin, M.D., M.P.A., FRCP-E, FRPych
CEO and Medical Director
American Psychiatric Association