OMB Control Number: 0938-1401 Expiration Date: 03/31/2022

Standard Notice and Consent Documents Under the No Surprises Act

Instructions

The Department of Health and Human Services (HHS) developed standard notice and consent documents under section 2799B-2(d) of the Public Health Service Act (PHS Act). These documents are for use when providing items and services to participants, beneficiaries, enrollees, or covered individuals in group health plans or group or individual health insurance coverage, including Federal Employees Health Benefits (FEHB) plans by either:

- A nonparticipating provider or nonparticipating emergency facility when furnishing certain post-stabilization services, or
- A nonparticipating provider (or facility on behalf of the provider) when furnishing nonemergency services (other than ancillary services) at certain participating health care facilities.

These documents provide the form and manner of the notice and consent documents specified by the Secretary of HHS under 45 CFR 149.410 and 149.420. HHS considers use of these documents in accordance with these instructions to be good faith compliance with the notice and consent requirements of section 2799B-2(d) of the PHS Act, provided that all other requirements are met. To the extent a state develops notice and consent documents that meet the statutory and regulatory requirements under section 2799B-2(d) of the PHS Act and 45 CFR 149.410 and 149.420, the state-developed documents will meet the Secretary's specifications regarding the form and manner of the notice and consent documents.

These documents may not be modified by providers or facilities, except as indicated in brackets or as may be necessary to reflect applicable state law. To use these documents properly, the nonparticipating provider or facility must fill in any blanks that appear in brackets with the appropriate information. Providers and facilities must fill out the notice and consent documents completely and delete the bracketed italicized text before presenting the documents to patients.

In particular, providers and facilities must fill in the blanks in the "Estimate of what you may pay" section and the "More details about your estimate" section before presenting the documents to patients.

The standard notice and consent documents must be given physically separate from and not attached to or incorporated into any other documents. The documents must not be hidden or included among other forms, and a representative of the provider or facility must be physically present or available by phone to explain the documents and estimates to the individual, and answer any questions, as necessary. The documents must meet applicable language access requirements, as specified in 45 CFR 149.420. The provider or facility is responsible for

translating these documents or providing a qualified interpreter, as applicable, when necessary to meet those requirements. The standard notice must be provided on paper, or, when feasible, electronically, if selected by the individual. The individual must be provided with a copy of the signed consent document in-person, by mail or via email, as selected by the individual.

If an individual makes an appointment for the relevant items or services at least 72 hours before the date that the items and services are to be furnished, these notice and consent documents must be provided to the individual, or the individual's authorized representative, at least 72 hours before the date that the items and services are to be furnished. If the individual makes an appointment for the relevant items or services within 72 hours of the date the items and services are to be furnished, these notice and consent documents must be provided to the individual, or the individual's authorized representative, on the day the appointment is scheduled. In a situation where an individual is provided the notice and consent documents on the day the items or services are to be furnished, including for post-stabilization services, the documents must be provided no later than 3 hours prior to furnishing the relevant items or services.

NOTE: The information provided in these instructions is intended to be only a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance upon which it is based. Refer to the applicable statutes, regulations, and other interpretive materials for complete and current information.

Do not include these instructions with the standard notice and consent documents given to patients.

Paperwork Reduction Act Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. The valid OMB control number for this information collection is 0938-1401. The time required to complete this information collection is estimated to average 1.3 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.