

“No Surprise Act” and Implementing Regulations: Implications for Freestanding Radiation Oncology Centers

On July 1, the Departments of Health and Human Services (HHS), Labor, and Treasury (collectively, the Departments), along with the Office of Personnel Management (OPM), released the “[Requirements Related to Surprise Billing; Part I](#)” interim final rule (IFR), which is subject to a 60 day comment period. The IFR implements key provisions of the [No Surprise Act](#), which is intended to protect people from surprise bills and significant out-of-network cost-sharing for emergency services, services provided by out-of-network providers during an in-network facility visit, and air ambulance services.

This is the first of several rules to implement the No Surprise Act. The second part, which will establish an audit process for plan issuers, is expected by October 1, 2021, while the third (to be issued no later than December 27, 2021). will address the specifics of the Independent Dispute Resolution (“IDR”) process that will be used to determine payments between insurers and non-network providers for services subject to the Act.

Background: The No Surprise Act

The No Surprises Act contains key protections to hold consumers harmless from the cost of unanticipated out-of-network medical bills. Surprise bills arise in emergencies—when patients typically have little or no say in where they receive care. They also arise in non-emergencies when patients at in-network hospitals or other facilities receive care from ancillary providers (such as anesthesiologists) who are not in-network and whom the patient did not choose.

The key protections included in the Act include:

- **Health plans must cover bills for emergency services without prior authorization or other restriction.**
- **Appeal Rights.** The Act requires that federal external appeal rights apply if consumers feel their health plan has not correctly identified and covered a surprise medical bill.
- **Balance billing is prohibited.** Out-of-network providers for emergency services and out-of-network providers who render non-emergency services at an in-network hospital or other facility are not allowed to balance bill patients beyond the applicable in-network cost sharing amount. The Act puts the burden on out-of-network providers to determine a patient’s insurance status and the applicable in-network cost sharing for the service. Please note, however, that neither the Act nor the IFR prohibits balance billing in situations where balance billing is not a “surprise”: Balance billing is permitted in contexts that do not involve emergency services or the provision of services in an in-network facility.

- **The Act provides a mechanism for out-of-network providers and insurers to reach agreement regarding the amount to be paid by the insurer to the out of network provider for emergency services and services provided in an in-network setting, including a mechanism for Independent Dispute Resolution if agreement cannot be reached.**
- **An exception to the balance billing prohibition is available for certain services if advance notice and consent is provided.** The exception applies for certain non-emergency services if providers give prior written notice at least 72 hours in advance and obtain the patient’s written consent. However, this exception does not apply for certain ancillary services or for services provided by an out-of-network provider in an in-network facility if there is no in-network provider with privileges at the facility to provide the services.
- **Specific oversight and enforcement activities are required.** States may enforce the Act against health plans they regulate (non-group health plans and fully-insured employer-sponsored plans), with federal fallback enforcement required if states fail to enforce. The federal government has primary responsibility for oversight and enforcement with respect to self-insured group health plans (e.g. ERISA plans)
- **Other provisions of the Act.** The Act includes several other provisions to help consumers get information in advance about how their health plan will work in practice, and to promote transparency of medical care prices generally.
 - **Health plans must provide an advanced explanation of benefits.** Also beginning in 2022, consumers can request advance information about how services will be covered before they are provided.
 - **Health plans must provide transitional continuity of coverage when a provider leaves the network.** The transitional coverage requirement applies to treatment for serious or complex health conditions, institutional or inpatient care, nonelective surgery, pregnancy, and care for patients with terminal illness.
 - **Health plans must maintain accurate provider network directories.**
 - **Health plans must disclose information about broker commissions.**

Major Provisions of the IFR

- The IRF addresses the details of determining the scope of the balance billing prohibitions, including, for example, defining relevant terms, and establishing a methodology for defining and implementing out-of-network consumer cost-sharing.

- ***Prohibition on Coverage Limits for Emergency Services.*** Under the IFR, any covered in-network and out of network emergency services must be covered without prior authorization or other coverage restrictions (with certain exceptions). “Emergency services” are defined broadly to include emergency services provided at urgent care centers permitted by state licensing laws to provide emergency services, and health plans cannot deny emergency services based solely on a diagnosis, which occurs frequently.
- ***Non-Emergency Services at In-Network Healthcare Facilities.*** The IFR sets forth rules under which health care facilities and providers are prohibited from charging out-of-network cost-sharing for non-emergency services obtained at an in-network facility by an out-of-network provider. This provision is intended to prevent situations where a beneficiary goes to an in-network health care facility, but a member of the care team (e.g., the anesthesiologist) is out-of-network. The IFR defines “health care facilities” to include hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgery centers, but solicits comments on whether there are other facilities that should fall within the definition of “health care facilities.”
- ***Applicability to Off-Site Services Associated with In-Network Facility Services.*** The IFR balance billing protections cover all services provided at the in-network facility, as well as “the furnishing of equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services,” associated with the visit, regardless of whether the provider furnishing such items or services is at the facility. This statement captures items and services ordered at the in-network facility but potentially provided by out-of-network providers. For example, any radiology service ordered by the in-network facility that may be sent to an off-site/out-of-network imaging center would be considered part of the in-network “visit” and would be covered by the balance billing protections of the IFR.
- ***Out of Network Rate Paid to Facilities.*** Under the IFR, the total amount paid to the out-of-network facility is determined in the following manner:
 - The amount allowed under an applicable All-Payer Model Agreement (e.g. Maryland), which some states may have entered into with HHS;
 - If no such All-Payer Model Agreement exists, an amount determined by state law;
 - An amount agreed by the provider and the payer.
 - If no rate agreement is reached, an amount is determined by an independent dispute resolution (IDR) entity. Of note, this IFR does not set forth the IDR process. Further rulemaking will establish the specifics of the IDR process.
- ***Out of Network Cost Sharing.*** Cost-sharing amounts must not be higher than in-network levels. If neither an All Payer Model nor a state rate exists, the lesser amount of either the

billed charge or the qualifying payment amount (“QPA”) (generally the 2019 median contracted rate for the same or similar service or item, facility type, and provider specialty, in the same geographic region, indexed for inflation or an alternate rate, with an alternative rate methodology applicable if fewer than three contracted rates are available.)

- ***Notice and Consent Exception to Balance Billing Prohibition.*** The IFR provides an exception to the balance billing and cost-sharing protections for certain post-stabilization services and non-emergency services, so long as the facility meets notice and consent requirements. To meet these requirements, the facility must provide written notice to the beneficiary in a form specified by HHS that includes a good faith estimate of the out-of-pocket costs. The notice must clearly state that the individual is not required to consent to receive such items or services from the nonparticipating provider or nonparticipating emergency facility. The provider or facility must also receive consent, via a live or electronic signature, on an HHS-specified form. Of note, this notice and consent exception does not apply to all situations. Specifically, the notice and consent exception does not apply to: (i) ancillary services, which include items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner; (ii) items and services provided by assistant surgeons, hospitalists, and intensivists; (iii) diagnostic services, including radiology and laboratory services; and (iv) items and services provided by a nonparticipating provider, only if there is no participating provider who can furnish such item or service at such facility.

Implications for Radiation Oncologists and Freestanding Radiation Oncology

The No Surprise Act and implementing regulations have a number of implications for radiation oncologists and freestanding radiation oncology centers and their patients. On the whole, the regulations interpret the limits on balance billing imposed by the Act in a manner intended to offer the broadest possible protection to patients, and patients of AFROC members who need emergency care or frequently need inpatient or outpatient hospital services are likely to benefit from the limits on balance billing in the regulations.

There are at least two situations in which the limitations imposed by the Act and IFR may be relevant to radiation oncologists and freestanding radiation oncology centers. The first arises when a freestanding center agrees to provide radiation oncology services to patients enrolled in a health plan in which the hospital participates but the radiation oncology center doesn't. In that case (and assuming that the center's arrangement with the hospital allows the center to bill the patient and plan directly), the limits on balance billing in the No Surprise Act may apply. In addition, these limits apply if an out-of-network radiation oncologist provides radiation oncology services in an in-network hospital. The limits on balance billing in this case may be waived upon notice and consent by the patient only if there is an in-network radiation oncologist who has staff privileges and can provide treatment.

Finally, AFROC members may wish to urge their patients to make use of those provisions of the Act that require health plans to provide advance determinations of coverage and estimated costs, especially for services that are considered experimental or investigational and are often subject to retroactive denial.