

named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, skin patches for treatment of hyperhidrosis are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for skin patches for treatment of hyperhidrosis. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 878.4425 to subpart E to read as follows:

§ 878.4425 Skin patch for treatment of hyperhidrosis.

(a) *Identification.* A skin patch for treatment of hyperhidrosis is a prescription topical patch that utilizes a chemical reaction to generate thermal energy in situ for treatment of hyperhidrosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and evaluate:

(i) Reduction in hyperhidrosis using a validated measure;

(ii) All adverse events; and

(iii) Impact of residual chemical on the skin.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Thermal reactivity of the active device component(s);

(ii) The total energy and energy flux (energy per unit area) of the device that is available to induce heating based on calorimetry; and

(iii) Characterization of the distribution and homogeneity of the chemical(s) on and within the device.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance testing must support the shelf life of the device by demonstrating device functionality and package integrity over the labeled shelf life.

(5) Patient and physician labeling must include:

(i) A summary of the clinical performance testing conducted with the device;

(ii) A listing of known risks including local adverse events, systemic effects,

and adverse changes in perspiration; and

(iii) Information about the known duration of effect.

(6) Physician labeling must also include:

(i) Instructions for safe disposal of the device; and

(ii) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13139 Filed 6–29–26; 8:45 am]

BILLING CODE 4164–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans to prescribe the spreads component of the interest assumption under the asset allocation regulation for plans with valuation dates of July 31, 2026–October 30, 2026. These interest assumptions are used for valuing benefits under terminating single-employer plans and for other purposes.

DATES: Effective July 31, 2026.

FOR FURTHER INFORMATION CONTACT: Jose Singer-Freeman (singer-freeman.jose@pbgc.gov), Attorney, Legislative and Regulatory Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101, 202–229–5432. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions—including an interest assumption—for valuing benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumption is also posted on PBGC's website (www.pbgc.gov).

PBGC uses the interest assumption in § 4044.54 to determine the present value of annuities in an involuntary or

distress termination of a single-employer plan under the asset allocation regulation. The assumptions in part 4044 of PBGC's regulations are also used in other situations where it is appropriate for liabilities to align with private sector group annuity prices. For example, PBGC's regulations on Notice, Collection, and Redetermination of Withdrawal Liability (29 CFR part 4219) and Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281) provide that these assumptions are used to value liabilities for purposes of determining withdrawn employers' reallocation liability in the event of a mass withdrawal from a multiemployer plan. Multiemployer plans that receive special financial assistance under the regulation on Special Financial Assistance by PBGC (29 CFR part 4262) must, as a condition of receiving special financial assistance, use the interest assumption to determine withdrawal liability for a prescribed period. Additionally, plan sponsors are required to use some, or all of these assumptions for specified purposes (*e.g.*, reporting benefit liabilities in filings required under PBGC's regulation on Annual Financial and Actuarial Information Reporting (29 CFR part 4010) or determining certain amounts to transfer to PBGC's Missing Participants Program on behalf of a missing participant of a terminating defined benefit plan under PBGC's regulation on Missing Participants (29 CFR part 4050)) and may use them for other purposes (*e.g.*, to ensure that plan spinoffs comply with section 414(l) of the Internal Revenue Code).

Part 4044 of PBGC's regulations provides that the interest assumption for part 4044 purposes is a yield curve (*i.e.*, the "4044 yield curve") that is based on a blend of two publicly available bond yield curves that is adjusted to the extent necessary so that the resulting liabilities align with group annuity prices. The adjustments are referred to as "spreads." PBGC determines and publishes spreads quarterly based on survey data on pricing of private-sector group annuities. PBGC posts the 4044 yield curve on its website at www.pbgc.gov each month shortly after its underlying data becomes available. In addition, practitioners are able to determine the 4044 yield curve as of the end of any month using the publicly available bond yield curves and the spreads specified in the regulation. This rule amends the regulation to specify the spreads used to determine the 4044 yield curve as of the last days of July, August, and September of 2026 (*i.e.*, the "third quarter 2026 spreads"). Due to space constraints, table 1 to paragraph (e) shows spreads only for the most recent four quarters. Historical spreads are available on www.pbgc.gov, along with more recent spreads.

Need for Immediate Guidance

PBGC has determined that notice of, and public comment on, this rule are impracticable, unnecessary, and contrary to the public interest. PBGC routinely updates the spreads component of the interest assumption in the asset allocation regulation so that the 4044 yield curve may be determined as soon as the underlying bond yield curves become available. These amendments are merely technical; they

ensure that use of PBGC's interest assumption continues to yield liabilities in line with group annuity prices. Accordingly, PBGC finds that the public interest is best served by issuing this rule expeditiously, without an opportunity for notice and comment, and that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.
For the reasons stated in the preamble, PBGC amends 29 CFR part 4044 as follows.

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 2. In § 4044.54, revise table 1 to paragraph (e) to read as follows:

§ 4044.54 Interest assumptions.

	*	*	*	*	*
(e)	*	*	*		
(3)	*	*	*		

TABLE 1 TO PARAGRAPH—SPREADS

Maturity point	Fourth quarter 2025 spreads (percent)	First quarter 2026 spreads (percent)	Second quarter 2026 spreads (percent)	Third quarter 2026 spreads (percent)
0.5	0.49	0.56	0.63	0.71
1.0	0.49	0.56	0.63	0.71
1.5	0.49	0.56	0.62	0.70
2.0	0.49	0.56	0.62	0.70
2.5	0.49	0.55	0.62	0.69
3.0	0.49	0.55	0.62	0.69
3.5	0.48	0.54	0.60	0.68
4.0	0.48	0.54	0.60	0.68
4.5	0.47	0.53	0.59	0.66
5.0	0.47	0.53	0.59	0.66
5.5	0.46	0.52	0.57	0.64
6.0	0.46	0.52	0.57	0.64
6.5	0.44	0.50	0.54	0.61
7.0	0.44	0.50	0.54	0.61
7.5	0.43	0.48	0.52	0.59
8.0	0.43	0.48	0.52	0.59
8.5	0.41	0.45	0.49	0.55
9.0	0.41	0.45	0.49	0.55
9.5	0.39	0.43	0.46	0.52

TABLE 1 TO PARAGRAPH—SPREADS—Continued

Maturity point	Fourth quarter 2025 spreads (percent)	First quarter 2026 spreads (percent)	Second quarter 2026 spreads (percent)	Third quarter 2026 spreads (percent)
10.0	0.39	0.43	0.46	0.52
10.5	0.37	0.40	0.43	0.48
11.0	0.37	0.40	0.43	0.48
11.5	0.34	0.37	0.39	0.44
12.0	0.34	0.37	0.39	0.44
12.5	0.32	0.34	0.36	0.40
13.0	0.32	0.34	0.36	0.40
13.5	0.30	0.31	0.32	0.36
14.0	0.30	0.31	0.32	0.36
14.5	0.27	0.28	0.28	0.32
15.0	0.27	0.28	0.28	0.32
15.5	0.25	0.25	0.24	0.28
16.0	0.25	0.25	0.24	0.28
16.5	0.23	0.22	0.21	0.23
17.0	0.23	0.22	0.21	0.23
17.5	0.20	0.19	0.17	0.19
18.0	0.20	0.19	0.17	0.19
18.5	0.18	0.16	0.13	0.15
19.0	0.18	0.16	0.13	0.15
19.5	0.16	0.13	0.10	0.11
20.0	0.16	0.13	0.10	0.11
20.5	0.14	0.11	0.07	0.08
21.0	0.14	0.11	0.07	0.08
21.5	0.12	0.08	0.04	0.04
22.0	0.12	0.08	0.04	0.04
22.5	0.10	0.06	0.01	0.01
23.0	0.10	0.06	0.01	0.01
23.5	0.08	0.04	−0.02	−0.02
24.0	0.08	0.04	−0.02	−0.02
24.5	0.07	0.02	−0.04	−0.05
25.0	0.07	0.02	−0.04	−0.05
25.5	0.06	0.00	−0.06	−0.07
26.0	0.06	0.00	−0.06	−0.07
26.5	0.05	−0.01	−0.08	−0.09
27.0	0.05	−0.01	−0.08	−0.09
27.5	0.04	−0.02	−0.09	−0.10
28.0	0.04	−0.02	−0.09	−0.10
28.5	0.03	−0.03	−0.10	−0.11
29.0	0.03	−0.03	−0.10	−0.11
29.5	0.03	−0.03	−0.10	−0.11
30.0	0.03	−0.03	−0.10	−0.11

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Joseph Krettek,*Assistant General Counsel, Pension Benefit Guaranty Corporation.*

[FR Doc. 2026–13124 Filed 6–29–26; 8:45 am]

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**DEPARTMENT OF HOMELAND
SECURITY****Coast Guard****33 CFR Parts 140 and 146****46 CFR Parts 4 and 109****[Docket No. USCG–2013–1057]****RIN 1625–AB99****Marine Casualty Reporting on the
Outer Continental Shelf****AGENCY:** Coast Guard, DHS.**ACTION:** Final rule.

SUMMARY: This final rule revises marine casualty reporting criteria for Outer Continental Shelf (OCS) activities to focus on characteristics of the involved entity rather than location of the

casualty. It also raises the property damage dollar threshold (PDT) for reporting marine casualties involving fixed OCS facilities from \$25,000 to \$75,000 and aligns other OCS units with that threshold, consistency with the PDT for vessels in U.S. waters. The rule reduces costs to U.S. industry by \$10,775 over 10 years and better harmonizes reporting requirements between U.S. and foreign floating offshore facilities, mobile offshore drilling units, and vessels engaged in OCS activities.

DATES: This final rule is effective July 30, 2026.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2013–1057 in the search box and click