(Pub. L. 113–235), supported a listening meeting between FDA and the regulated industries to consider alternative solutions to the proposed rule on safety labeling that will meet all public health goals relating to multisource drugs (see https://www.congress.gov/congressional-record/2014/12/11/house-section/article/H9307-1) (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register).

In view of these requests and to promote transparency, FDA will hold a public meeting at which any stakeholders may present or comment on the proposed rule or any alternative proposals intended to improve communication of important newly acquired drug safety information to health care professionals and the public.

In addition, FDA is reopening the comment period for the proposed rule (78 FR 67985) until April 27, 2015, to receive submissions of additional written comments on the proposed rule as well as alternative proposals presented during the public meeting.

II. Registration and Requests for Oral Presentations

If you would like to attend the public meeting, please register for the meeting by email to CBESupplements.PublicMeeting@fda.hhs.gov by March 20, 2015. The email should contain complete contact information for each attendee (including name, title, firm name or affiliation, address, email, telephone and fax numbers). Those without email access can register by contacting Ellen Molinaro (see FOR FURTHER INFORMATION CONTACT) by March 20, 2015. There is no fee to register for the meeting, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration on the day of the meeting also will be permitted on a space-available basis beginning at 7:30 a.m.

Individuals who wish to present at the public meeting must register on or before March 16, 2015, and provide complete contact information, including name, title, firm name or affiliation, address, email, telephone and fax numbers. You should provide a brief description of your presentation, and indicate the approximate desired length of your presentation, so that FDA can consider these in organizing the presentations. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available and the approximate time their presentation is scheduled to begin. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make a presentation. An agenda will be posted on the FDA Web site at http://www.fda.gov/Drugs/NewsEvents/ucm431265.htm prior to the meeting. Presenters are encouraged to submit a copy of their presentation and related written material to the docket (see “Comments”) in advance of the public meeting.

If you need special accommodations because of a disability, please contact Ellen Molinaro (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

III. Streaming Webcast of the Public Meeting

This public meeting will also be Webcast. Information about how to view the live Webcast of this meeting will be posted on the FDA Web site at http://www.fda.gov/Drugs/NewsEvents/ucm431265.htm prior to the meeting.

IV. Comments

Interested persons may submit either electronic comments regarding proposed alternatives to the proposed rule to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Electronic or written comments will be accepted after the public meeting until April 27, 2015.

V. Transcripts

Please be advised that as soon as possible after a transcript of the public meeting is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter dated November 14, 2014, from Mr. Neas (GPhA) and Mr. Castellani (PhRMA) to Dr. Hamburg (FDA) regarding request for listening meeting on Expedited Agency Review proposal.


Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2015–03211 Filed 2–17–15; 8:45 am]  
BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1  
[REG–102648–15]  
RIN 1545–BM66

Request for Information on Suspensions of Benefits Under the Multiemployer Pension Reform Act of 2014

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Request for information.

SUMMARY: The Department of the Treasury invites public comments with regard to future guidance required to implement provisions of the Multiemployer Pension Reform Act of 2014, Division O of the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235 (MPRA). MPRA generally permits a sponsor of a multiemployer defined benefit plan that is in critical and declining status to suspend certain benefits following the approval of an application for suspension, consideration of public comments, approval of an application for suspension, and satisfaction of other specified conditions (including a participant vote).

DATES: Comments must be received by April 6, 2015.

ADDRESSES: Send submissions to: CCPA:LPD:PR (REG–102648–15), Room 5205, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CCPA:LPD:PR (REG–102648–15), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue NW,
Section 212 of the Pension Protection Act of 2006, Public Law 109–280 (120 Stat. 780 (2006)) (PPA ’06) added section 432 of the Internal Revenue Code (Code), which prescribes funding rules for certain multiemployer defined benefit plans in endangered and critical status and permits plans in critical status to be amended to reduce certain otherwise protected benefits (referred to as “adjustable benefits”). Section 202 of PPA ’06 amended section 305 of the Employee Retirement Income Security Act of 1974, Public Law 93–406 (88 Stat. 829 (1974)), as amended (ERISA), to prescribe parallel rules. PPA ’06 provided that section 432 and ERISA section 305 would sunset for plan years beginning after December 31, 2014. However, section 101 of MPRA made them permanent, with certain modifications.

Section 201 of MPRA amended Code section 432 to add a new status, called “critical and declining status,” for multiemployer defined benefit plans. Section 432(b)(6) provides that a plan in critical status is treated as being in critical and declining status if the plan satisfies the criteria for critical status, and in addition is projected to become insolvent within the meaning of section 418E during the current plan year or any of the 14 succeeding plan years (or 19 succeeding plan years if the plan has a ratio of inactive participants to active participants that exceeds two to one or if the funded percentage of the plan is less than 80 percent).1

Section 201 of MPRA also amended section 432(e)(9) to prescribe benefit suspension rules for multiemployer defined benefit plans in critical and declining status. Section 432(e)(9)(A) provides that notwithstanding section 411(d)(6) and subject to the requirements of section 432(e)(9)(B) through (I), the plan sponsor of a plan in critical and declining status may, by plan amendment, suspend benefits that the sponsor deems appropriate. Section 432(e)(9)(B) defines “suspension of benefits” as the temporary or permanent reduction of any current or future payment obligation of the plan, whether or not in pay status at the time of the suspension of benefits, and sets forth other rules relating to suspensions. In the case of plans with 10,000 or more participants, section 432(e)(9)(B) requires the plan sponsor to select a plan participant in pay status (who may also be a plan trustee) to act as a retiree representative throughout the suspension approval process.

Section 432(e)(9)(C) prescribes the conditions that must be satisfied before a plan sponsor may suspend benefits. For example, section 432(e)(9)(C)(i) provides that the plan actuary must certify, taking into account the proposed suspensions of benefits and, if applicable, a proposed partition of the plan under section 4233 of ERISA, that the plan is projected to avoid insolvency within the meaning of section 418E, assuming the suspensions of benefits continue until the suspensions of benefits expire by their own terms or, if no such expiration is set, indefinitely. Section 432(e)(9)(D) contains limitations on the benefits that may be suspended. For example, section 432(e)(9)(D)(ii) limits the applicability of a suspension in the case of a participant or beneficiary who has attained age 75 as of the effective date of the suspension and section 432(e)(9)(D)(iii) provides that no benefits based on disability (as defined under the plan) may be suspended.

Section 432(e)(9)(E) prescribes rules relating to possible benefit improvements while a suspension of benefits is in effect. Section 432(e)(9)(F) contains notice requirements associated with a suspension of benefits. These include the requirement under section 432(e)(9)(F)(i) that no suspension of benefits may be made unless notice to specified parties of the proposed suspension has been given by the plan sponsor (in the form and manner to be prescribed in guidance) concurrently with an application for approval of the suspension. Section 432(e)(9)(G) describes the process for approval or rejection of a plan sponsor’s application for a suspension of benefits, including that the Treasury Secretary, in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Secretary of Labor, shall approve an application upon finding that the plan is eligible for the suspension and has satisfied the criteria of section 432(e)(9)(C), (D), (E), and (F). As part of this process, section 432(e)(9)(G)(ii) requires the publication of a request for comments within 30 days after receipt of an application for suspension of benefits, and section 432(e)(9)(G)(iii), (iv) and (v) prescribes rules for agency action and review of the application.

Section 432(e)(9)(H) contains rules relating to the participant vote that is required before any suspension of benefits may take effect, with special rules for systemically important plans. The special rules include an opportunity for the Participant and Plan Sponsor Advocate selected under section 4004 of ERISA to submit recommendations with respect to a suspension in certain circumstances. Section 432(e)(9)(I) contains provisions relating to judicial review.

An application for approval of a plan amendment to suspend benefits may be made in combination with an application to the PBGC for a partition of the plan, and a plan sponsor also may ask the PBGC for technical or financial assistance with a merger. The PBGC is issuing its own request for information to seek comment on the processes associated with applying for partition or merger assistance, including how such processes should be coordinated with the benefit suspension process. The agencies will coordinate on the development of processes that will apply to applications falling within their respective jurisdictions.

Request for Information

Comments are requested on matters that may be addressed in future guidance implementing section 432(e)(9), and in particular on the following:

1. How should future guidance address actuarial and other issues, including duration, related to the following certifications and determinations:

a. The actuary’s certification under section 432(b)(3) that a multiemployer plan is in critical and declining status;

b. The actuary’s section 432(e)(9)(C)(i) projection of continued solvency (taking into account the proposed suspension and, if applicable, a proposed partition under section 4233 of ERISA); and

c. The plan sponsor’s section 432(e)(9)(C)(ii) determination that the plan is projected to become insolvent unless benefits are suspended?

2. For purposes of the section 432(e)(9)(D)(iii) limitation that a suspension is not permitted to apply to benefits based on disability (as defined

1Section 201(a) of MPRA makes parallel amendments to section 305 of ERISA. Under section 101 of Reorganization Plan No. 4 of 1978 (43 FR 47713), the Department of the Treasury has interpretive jurisdiction over the subject matter of this document for purposes of ERISA as well as the Code.
under the plan), how can a plan sponsor identify which benefits are based on disability?

3. For participants who have not yet retired:
   a. What practical issues should be considered as a result of the fact that their benefits are not yet fixed (for example, their benefits could vary as a result of future accruals, when they decide to retire and which optional form of benefit they select)?
   b. What practical issues should be considered in the case of a suspension of benefits that is combined with a reduction of future accruals or a reduction of section 432(e)(8) adjustable benefits (such as subsidized early retirement factors) under a rehabilitation plan?

4. For participants who have retired, what practical issues should be considered regarding the section 432(e)(9)(D)(ii) age limitations on suspensions, the application of the section 432(e)(9)(E) rules on benefit improvements, or other provisions?

5. With respect to the section 432(e)(9)(F) requirement to provide notice of the proposed suspension to plan participants and beneficiaries concurrently with the submission of the application for approval:
   a. What suggestions do commenters have for the steps that are needed to satisfy the requirement to provide notice to the plan participants and beneficiaries “who may be contacted by reasonable efforts,” including the application of that requirement to terminated vested participants?
   b. What practical issues do plan sponsors anticipate in providing individual estimates of the effect of the proposed suspensions on each participant and beneficiary?
   c. If the suspension is combined with other reductions as described in request number 3.b, how will the notice of proposed suspension interact with the notices required for those other reductions?
   d. What issues arise in coordinating benefit protections that are measured as of the date of suspension (such as the restriction on suspensions that apply to a participant or beneficiary who has attained age 75 as of the effective date of the suspension) with the timing of the application, notice, and voting process?

6. With respect to item 5, please provide any examples of notices of proposed suspension that commenters would like to be considered in the development of a model notice.

7. What issues arise in connection with the section 432(e)(9)(G)(ii) requirement to solicit comments on an application for suspension of benefits?

a. Should the comments received from contributing employers, employee organizations, participants and beneficiaries, and other interested parties be made available to the public?

b. How long should the comment period last?

8. With respect to the section 432(e)(9)(H) participant vote, what issues arise in connection with:
   a. Preparing the ballot, including developing a statement in opposition to the suspension compiled from comments and obtaining approval of the ballot within the statutory time constraints for conducting a vote; and
   b. Conducting the vote and obtaining certification of the results of the vote?

9. What other practical issues do commenters anticipate will arise in the course of implementing these provisions?

Timing of Applications and Notices

Section 201(b)(7) of MPRA provides that, not later than 180 days after the date of the enactment of this Act, the Treasury Secretary, in consultation with the Pension Benefit Guaranty Corporation and the Secretary of Labor, shall publish appropriate guidance to implement section 432(e)(9). In addition, section 432(e)(9)(F)(i) provides that no suspension of benefits may be made unless notice of the proposed suspension has been given by the plan sponsor concurrently with an application for approval of the suspension, and section 432(e)(9)(F)(ii) provides that notice must be “provided in a form and manner prescribed in guidance.” Section 432(e)(9)(G)(i) provides that the Treasury Secretary, in consultation with the Pension Benefit Guaranty Corporation and the Secretary of Labor, shall approve an application for suspension upon finding that the plan has satisfied the criteria of section 432(e)(9)(C), (D), (E), and (F). Because appropriate guidance is required to implement section 432(e)(9), including the procedures for the plan sponsor to submit an application for approval of a suspension of benefits and provide concurrent notice, a plan sponsor should not submit an application for a suspension of benefits until a date specified in that future guidance.


David G. Clunie,
Executive Secretary, Department of the Treasury.

DEPARTMENT OF JUSTICE
Office of the Attorney General

28 CFR Part 11

[JMD Docket No. 152; A.G. Order No. 3493–2015]

RIN 1105–NYD

Department of Justice Debt Collection Regulations

AGENCY: Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes to amend the regulations that govern debt collection at the Department of Justice (Department) to bring the regulations into conformity with government-wide standards, to update or delete obsolete references, and to make other clarifying or technical changes.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before April 20, 2015. Comments received by mail will be considered timely if they are postmarked on or before that date. The electronic Federal Docket Management System (FDMS) will accept comments until Midnight Eastern Time at the end of that day.

ADDRESSES: The Department encourages all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to http://www.regulations.gov will be posted for public review and are part of the official docket record. Should you wish to submit written comments via regular or express mail, however, they should be sent to: Dennis Dauphin, Director, Debt Collection Management Staff, Justice Management Division, U.S. Department of Justice, Washington, DC 20530.

FOR FURTHER INFORMATION CONTACT:
Dennis Dauphin, Director, Debt Collection Management Staff, or Morton J. Posner, Assistant General Counsel, Justice Management Division, U.S. Department of Justice, Washington, DC 20530, (202) 514–5343 or (202) 514–3452.

SUPPLEMENTARY INFORMATION: This rule updates the Department’s debt collection regulations at 28 CFR part 11, subpart A—Retention of Private Counsel for Debt Collection, Subpart B—