Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78j–3, 78l, 78m, 78n, 78n–1, 78o, 78u–5, 78w, 78ll, 78 mm, 80a–8, 80a–9, 80a–20, 80a–29, 80a–30, 80a–31(c), 80a–37, 80a–38(a), 80a–39, 80b–11 and 7201 *et seq.* 18 U.S.C. 1350; Sec. 953(b), Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3), Pub. L. 112–106, 126 Stat. 309; and Sec. 84001, Pub. L. 114–94, 129 Stat. 1312.

* * * * *

§ 229.1100 [Amended]

■ 2. Amend § 229.1100 in paragraph (a) by removing ''(§§ 229.1100 through 229.1123)'' and adding in its place ''(§§ 229.1100 through 229.1125)''.

§ 229.1104 [Amended]

■ 3. Amend § 229.1104 in paragraph (e)(2) by adding ''in response to Rule 15Ga–1'' after ''(as that term is defined in Section 15G(a) of the Securities Exchange Act of 1934)''.

§ 229.1105 [Amended]

■ 4. Amend § 229.1105 in paragraph (a)(3)(ii) by removing ''135 days after'' and adding in its place ''135 days of''.

§ 229.1115 [Amended]

■ 5. Amend § 229.1115 in Instruction 1 to Item 1115 by removing '', 3 and 5 to Item 1114'' and adding in its place ''and 4 to Item 1114(b)''.

§ 229.1125 [Amended]

■ 6. Amend Appendix to § 229.1125—Schedule AL in Item 4(i) and Item 4(j) by removing all references to ''loan'' and adding in their place ''lease''; and removing all references to ''loans'' and adding in their place ''leases''.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 7. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77d note, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l,* 78m, 78n, 78*o,* 78*o*–7 note, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

§ 230.405 [Amended]

■ 8. Amend § 230.405 in paragraph (1)(i) of the definition of an *Ineligible issuer,* by removing the phrase ''General Instruction I.A.4 of Form S–3'' and adding in its place ''General Instruction I.A.2 of Form SF–3''

§ 230.456 [Amended]

■ 9. Amend § 230.456 in paragraph (c)(3) by removing ''post-effective amendment or''.

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 10. The authority citation for part 239 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78*l,* 78m, 78n, 78o(d), 78o–7 note, 78u–5, 78w(a), 78*ll,* 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, 80a–37, and Sec. 71003 and Sec. 84001, Pub. L. 114–94, 129 Stat. 1312, unless otherwise noted.

§ 239.45 [Amended]

■ 11. Amend Form SF–3 (referenced in § 239.45) in Note 2 of Notes to the ''Calculation of Registration Fee'' Table (''Fee Table'') by removing ''in a post-effective amendment to the registration statement or''.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 12. The authority citation for part 249 continues to read, in part, as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* 12 U.S.C. 5461 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

§ 249.308 [Amended]

■ 13. Amend Form 8–K (referenced in § 249.308) by amending Item 6.05 to remove ''Form S–3 (17 CFR 239.13)'' and add in its place ''Form SF–3 (17 CFR 239.45)''.

§ 249.312 [Amended]

■ 14. Amend Form 10–D (referenced in § 249.312) by amending Item 1 in Part I:

■ a. to remove all references to the phrase ''Item 1121(a) and (b)'' and replacing them with the phrase ''Item 1121(a), (b) and (c)''; and

■ b. to remove the phrase ''17 CFR 229.1121(a) and (b)'' and add in its place ''17 CFR 1121(a), (b) and (c)''.

Dated: June 16, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–14730 Filed 6–21–16; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2014–N–1484]

Revisions to Exceptions Applicable to Certain Human Cells, Tissues, and Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency or we) is issuing this final rule to amend certain regulations regarding donor eligibility, including the screening and testing of donors of particular human cells, tissues, and cellular and tissue-based products (HCT/Ps), and related labeling. This final rule is in response to our enhanced understanding in this area and in response to comments from stakeholders regarding the importance of embryos to individuals and couples seeking access to donated embryos.

DATES: This rule is effective August 22, 2016.

ADDRESSES: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule to amend certain regulations regarding donor eligibility, including the screening and testing of donors of particular HCT/Ps, and related labeling. We are finalizing these changes in response to our enhanced understanding in this area and in response to comments from stakeholders regarding the importance of embryos to individuals and couples seeking access to donated embryos.

B. Summary of the Major Provisions of the Final Rule

FDA is amending existing regulations to provide additional flexibility to HCT/P establishments to make available for reproductive use embryos originally intended for reproductive use for a specific individual or couple when those embryos are subsequently intended for directed or anonymous donation. Specifically, this rulemaking redesignates the current Title 21 of the Code of Federal Regulations (CFR) 1271.90(b) (§ 1271.90(b)) to new § 1271.90(c), and would insert a new § 1271.90(b) entitled ''Exceptions for reproductive use'' to clarify that if an embryo was originally intended for reproductive use for a specific individual or couple, its use for directed or anonymous donation, would not be prohibited under § 1271.45(c), even when the applicable donor eligibility requirements under part 1271, subpart C, are not met. FDA also clarifies that we are not creating an exception for deficiencies that occurred in making the donor eligibility determination for either the oocyte donor or the semen donor as required under § 1271.45(b), or for deficiencies in performing donor screening or testing, as required under §§ 1271.75, 1271.80, and 1271.85.

The final rule also requires appropriate labeling for embryos that would describe the donor eligibility status of the individual donors whose gametes were used to form the embryo. The content of the labeling is not different from that required under current regulations. Consistent with current regulations, the intent of the labeling is to help ensure that physicians have specific and accurate information to provide to recipients for use in making informed medical decisions.

C. Legal Authority

FDA has authority for this rulemaking under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). Under section 361 of the PHS Act, FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable disease between the States or from foreign countries into the States.

D. Costs and Benefits

Because this rule imposes no additional regulatory burdens, the costs associated with this rule are expected to be minimal.

II. Background

A. Need for the Regulation/History of This Rulemaking

Under the authority of section 361 of the PHS Act, by delegation from the Surgeon General and the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy agents. Certain diseases are transmissible through implantation, transplantation, infusion, or transfer of HCT/Ps derived from donors infected with those diseases. To prevent the introduction, transmission, or spread of such communicable diseases, we consider it necessary to require establishments to take appropriate measures to prevent the use of HCT/Ps from infected donors. FDA regulates HCT/Ps intended for implantation, transplantation, infusion, or transfer into a human recipient under part 1271 that was issued under the authority of section 361 of the PHS Act. Part 1271 requires HCT/P establishments to screen and test donors for relevant communicable disease agents and diseases, to prepare and follow written standard operating procedures for the prevention of the spread of communicable diseases, and to maintain records. Part 1271 also requires that for most HCT/Ps, the donor must be determined to be eligible, based on the results of screening and testing for relevant communicable disease agents and diseases. In most cases, a donor who tests reactive for a particular communicable disease, or who possesses clinical evidence of, or risk factors for, communicable disease agents and diseases, would be considered ineligible, and HCT/Ps from that donor would not ordinarily be used.

FDA has published three final rules that make up part 1271. In the **Federal Register** of January 19, 2001 (66 FR 5447), we published regulations requiring HCT/P establishments to register and list their HCT/Ps with FDA (registration final rule). In the **Federal Register** of May 25, 2004 (69 FR 29786), we published regulations requiring most donors to be tested and screened for relevant communicable disease agents and diseases (donor eligibility final rule). In the **Federal Register** of November 24, 2004 (69 FR 68612), we published regulations requiring certain HCT/P establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, recordkeeping, and the establishment of a quality program (CGTP final rule). These regulations apply to HCT/Ps recovered on or after May 25, 2005.

As part of our ongoing effort to implement our framework for regulating HCT/Ps, in the **Federal Register** of May 25, 2005 (70 FR 29949), we issued an interim final rule entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling'' (2005 interim final rule), which had an effective date simultaneous with publication. This interim final rule was then adopted without change in the **Federal Register** of June 19, 2007 (72 FR 33667), in the final rule entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling'' (2007 final rule). The 2007 final rule amended regulations regarding the screening and testing of donors of HCT/Ps, timing of specimen collection, record retention requirements, and related labeling requirements in response to public comments concerning the importance of cryopreserved embryos to individuals seeking access to donated embryos. The 2007 final rule also added an exception to the donor eligibility requirements in § 1271.90(a)(4) for cryopreserved embryos that, while originally exempt from the donor eligibility requirements because the donors were sexually intimate partners, are later intended for directed or anonymous donation.

In recent years, industry and the medical community have expressed concerns that the exception added by

the 2007 final rule does not fully address the need for access to cryopreserved embryos. The stakeholders have raised concerns that the current regulations still unduly restrict the use of embryos that were originally intended for personal reproductive use, and therefore impose limitations on individuals and couples involved in family building. In response to these concerns, FDA published the proposed rule ''Revisions to Exceptions Applicable to Certain Human Cells, Tissues, and Cellular and Tissue-Based Products'' in the **Federal Register** of December 31, 2014 (79 FR 78744). The proposed rule intended to increase access to embryos for reproductive use by expanding the current exceptions to the prohibitions on use under § 1271.90, providing HCT/P establishments with the flexibility to make available any embryo originally formed for reproductive use for a specific individual or couple and now intended for reproductive use in a directed or anonymous donation, provided that specific criteria are met, including requirements for labeling.

B. Summary of Comments to the Proposed Rule

We received approximately 10 comment letters on the proposed rule by the close of the comment period. We received comments from academia, professional organizations, and individuals. The comments were balanced between those expressing support for the proposed rule and those raising concerns about how the proposed exception will impact public health. They addressed the following topics: Purpose and scope of the final rule, donor screening, exceptions from the requirement of determining donor eligibility, and labeling requirements.

C. General Overview of the Final Rule

FDA is adopting as final, without material change, the proposed rule to amend certain regulations regarding donor eligibility and related labeling.

We are making revisions to the following FDA regulations:

1. Amendments to § 1271.90

Section 1271.90 sets forth exceptions where HCT/P establishments are not required to make a donor eligibility determination under § 1271.50 or to perform donor screening or testing under §§ 1271.75, 1271.80, and 1271.85. We are adding language to the exceptions listed in this section to provide clarity and update the regulation by allowing for an embryo originally intended for reproductive use for a specific individual or couple, to be subsequently used for directed or anonymous donation, even when the donor eligibility requirements under part 1271, subpart C are not met.

We are amending § 1271.90 as follows:

- Changing the heading of this section by deleting ''from the requirement of determining donor eligibility,'' and inserting ''other'' before ''exceptions.'' The heading for § 1271.90 will read ''Are there other exceptions and what labeling requirements apply?'' We made this change for clarity; the new heading will be more accurate.
- Changing § 1271.90(a)(3) by replacing ''exempt'' with ''excepted,'' which is the term used in the introductory title for this provision. Thus, this change will make the language more consistent. The beginning of § 1271.90(a)(3) will read, ''Cryopreserved cells or tissue for reproductive use, other than embryos, originally excepted . . . .''
- Changing current § 1271.90(a)(4) by replacing ''exempt'' with ''excepted''.
- Redesignating current § 1271.90(b) as § 1271.90(c) and adding a new paragraph (b) to § 1271.90.
- Changing newly designated § 1271.90(c) by removing ''paragraph (a)'' and adding in its place ''paragraphs (a) and (b)'' in the introductory text, revising § 1271.90(c)(2) to replace ''(b)(6)'' with ''(c)(6)'', and by adding ''recovery or'' before ''cryopreservation'' in new § 1271.90(c)(6) to clarify that some testing and screening activities may take place before recovery of the gametes, not just before cryopreservation of the embryos.

2. Section 1271.90(b)

We are redesignating the current § 1271.90(b) to § 1271.90(c), and adding a new § 1271.90(b) entitled ''Exceptions for reproductive use.'' Under finalized § 1271.90(b), an embryo originally intended for reproductive use for a specific individual or couple that is subsequently intended for directed or anonymous donation is excepted from the prohibition on use under § 1271.45(c) even when the applicable donor eligibility requirements under part 1271, subpart C are not met. Accordingly, when an establishment fails to comply with applicable donor eligibility requirements under part 1271, subpart C, the establishment will not be prohibited from making available for reproductive use such embryos for reproductive purposes in accordance with this section. The exception from the prohibition on use does not create an exception for deficiencies that occurred in making the donor eligibility determination for either the oocyte donor or the semen donor as required under § 1271.45(b), or for deficiencies in performing donor screening or testing, as required under §§ 1271.75, 1271.80, and 1271.85.

We note that the language we are adding to the exceptions currently listed in § 1271.90 is additive. It creates an additional exception for the use of certain reproductive HCT/Ps that are not currently excepted, but it does not impact or restrict the exceptions currently provided for in the regulations.

3. Section 1271.90(c)

Under § 1271.90(c), HCT/P establishments must prominently label an HCT/P described in § 1271.90(a) and (b). The labeling requirements are intended to help ensure that physicians have specific and accurate information to provide to recipients for use in making informed medical decisions.

The nonsubstantive change to § 1271.90(c)(2) clarifies that the labeling requirements contained in § 1271.90(c)(2) do not apply to reproductive cells or tissue labeled in accordance with § 1271.90(c)(6). The change to § 1271.90(c)(6) includes ''recovery or'' before the word ''cryopreservation''. Thus, the § 1271.90(c)(6) provision requires HCT/P establishments to prominently label an HCT/P described in § 1271.90(a)(3) or (a)(4) with ''Advise recipient that screening and testing of the donor(s) were not performed at the time of recovery or cryopreservation of the reproductive cells or tissue, but have been performed subsequently'' for HCT/Ps described in § 1271.90(a)(3) or (a)(4). This change is made to recognize that some testing and screening activities may take place even before recovery of HCT/Ps, not just before cryopreservation.

4. Amendment to § 1271.370

Section 1271.370 sets forth labeling requirements in addition to those that apply under §§ 1271.55, 1271.60, 1271.65, and 1271.90. Because, as discussed previously, this rule redesignates the current labeling requirements under § 1271.90(b) to § 1271.90(c), we are amending § 1271.370(b)(4) to revise the reference from § 1271.90(b) to § 1271.90(c).

III. Legal Authority

FDA is issuing this final rule under the authority of section 361 of the PHS Act (42 U.S.C. 264). Under section 361 of the PHS Act, FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable disease

between the States or from foreign countries into the States. It is important to recognize that HCT/Ps recovered in one State may be sent to another for processing, and then shipped for use throughout the United States, or beyond. FDA has been involved in many recalls where HCT/Ps processed in a single establishment have been distributed in many States. In any event, intrastate transactions affecting interstate communicable disease transmission may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews,* 427 F. Supp. 174, 176 (E.D. La. 1977); *Independent Turtle Farmers of Louisiana, Inc.* v. *United States of America, et al.,* 2010 U.S. Dist. LEXIS 31117). This final rule incorporates changes in response to our enhanced understanding of the uses of certain types of HCT/Ps in specific situations and in response to comments from stakeholders regarding the importance of embryos to individuals and couples seeking access to donated embryos.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

We received approximately 10 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from academia, professional organizations, and individual consumers.

We describe and respond to the comments in sections IV.B through IV.F. We have numbered each comment to help distinguish among different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which the comments were received.

B. Description of General Comments and FDA Response

Several comments made general remarks supporting the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) There were several comments that were in support of the proposed rule and suggested that we provide even more guidance on donor eligibility, screening, and testing of donors of reproductive cells. One suggestion was that FDA's donor eligibility, screening, and testing requirements closely parallel American Society of Reproductive Medicine/Society for Assisted Reproductive Technology guidelines.

(Response) FDA acknowledges and appreciates the supportive comments. We appreciate the interest in additional guidance for the screening and testing of donors of reproductive cells. We continue to review existing regulations with respect to providing additional guidance or modifying these regulations as appropriate, in the future.

(Comment 2) One comment asked if the final rule would be applied retrospectively to embryos formed and cryopreserved on or after May 25, 2005.

(Response) Yes, the final rule applies to embryos formed and cryopreserved on or after May 25, 2005.

C. Purpose and Scope of the Final Rule (§ 1271.1)

(Comment 3) One comment noted that preventing the spread of communicable disease protects the population and the family receiving the donation. Two comments suggested that the proposed rule conflicts with FDA regulations that serve to prevent the introduction, transmission, and spread of communicable disease. One comment expressed concern that the proposed rule appears to relax the testing requirements for donors and conflicts with the PHS Act, specifically section 361, that provides FDA with the authority to make and enforce regulations ''to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from State or possession into any other State or possession'' (42 U.S.C. 264(a)). This commenter's interpretation of the proposed rule is that it removes the requirement for reproductive tissue donors to be tested, and only requires reproductive tissue donor testing ''when possible.'' According to the comment, FDA seems to posit informed consent as an adequate response to the health risks faced by recipients of donated embryos. The commenter would like FDA to strike the qualifier ''when possible'' from the text of the proposed rule because the commenter believes this approach would provide a greater level of protection to the recipient than the proposed rule and preserve FDA's intention of relaxing the current donor eligibility regulations in the interest of family building.

(Response) As stated previously, we consider it necessary that establishments take appropriate measures to prevent the use of HCT/Ps from donors infected with communicable diseases. Part 1271 requires HCT/P establishments to screen and test donors for relevant communicable disease agents and diseases, and to maintain records. Part 1271 also requires for most HCT/Ps that the donor must be determined to be eligible, based on the results of screening and testing for relevant communicable disease agents and diseases. We have retained the qualifier ''when possible'' in § 1271.90(a)(4) to provide HCT/P establishments with the flexibility to make available any embryos originally formed for reproductive use for a specific individual or couple and now intended for reproductive use in a directed or anonymous donation, provided that specific criteria are met, including requirements for labeling.

The final rule provides for the continued applicability of labeling requirements for embryos intended for reproductive use that would be excepted from the prohibition on use. The rule requires prominent labeling that describes the donor eligibility status of the individual donors whose gametes were used to form the embryo. The required labeling will provide information to the treating physician to permit discussion of the potential risks of communicable disease with the recipient.

D. Donor Screening (§ 1271.75)

(Comment 4) Some of the comments expressed concern about the risk of accepting an unscreened donation. Another comment noted that eligibility of the HCT/P donor must be assessed prior to usage to ensure the safety of recipients, their offspring, and the public as a whole; and furthermore, ensuring the proper screening of the donor's HCT/P enables the control of the spread of disease.

(Response) We agree that the proper screening of HCT/P donors minimizes the risk of introducing, transmitting, or spreading communicable diseases. As stated in the proposed rule, we consider it necessary to require establishments to take appropriate measures to prevent the use of HCT/Ps from infected donors. Part 1271 requires HCT/P establishments to screen and test donors for relevant communicable disease agents and diseases, and to maintain records. Part 1271 also requires, for most HCT/Ps, that donor be determined to be eligible, based on the results of screening and testing for relevant communicable disease agents and diseases. In most cases, a donor who

tests reactive for a particular communicable disease, or who possesses clinical evidence of, or risk factors for, a communicable disease agent and disease, would be considered ineligible, and cells or tissues from that donor would not ordinarily be used.

(Comment 5) A few comments expressed the belief that the proposed rule will allow for better genetic profiling. One of those comments stated that labeling will make it easier to identify particular genotypes for research. Another comment stated that genetically profiling all donors and to the extent possible all embryos will reduce the risk of recipients of embryos giving birth to children with serious genetic disorders. The commenter asked FDA to require establishments to genetically screen all donors and the embryo when possible.

(Response) These comments address a topic that is outside the scope of this rulemaking.

E. Exceptions From the Requirement of Determining Donor Eligibility (§ 1271.90)

(Comment 6) One comment sought transparency as to which embryos are excepted and requested specific examples of how the rule provides additional flexibility to make embryos available for directed and anonymous donation. Specifically, the commenter asked whether donation would be allowed when the embryo was originally intended for transfer to a sexually intimate partner, where one of the gamete providers (either a directed or anonymous donor) would be considered ineligible based on screening and testing.

(Response) The rulemaking provides additional flexibility to make embryos available when there have been changes in the original plans for use of the embryos. Under finalized § 1271.90(b), an embryo originally intended for reproductive use for a specific individual or couple that is subsequently intended for directed or anonymous donation is excepted from the prohibition on use under § 1271.45(c) even when the applicable donor eligibility requirements under part 1271, subpart C are not met. Accordingly, when an establishment fails to comply with applicable donor eligibility requirements under part 1271, subpart C, the establishment will not be prohibited from making available for reproductive use such embryos for reproductive purposes in accordance with this section. The exception from the prohibition on use does not create an exception for deficiencies that occurred in making the donor eligibility determination for either the oocyte donor or the semen donor as required under § 1271.45(b), or for deficiencies in performing donor screening or testing, as required under §§ 1271.75, 1271.80, and 1271.85.

We note that the change we are making to the exceptions currently listed in § 1271.90 is additive. It creates an additional exception for the use of certain reproductive HCT/Ps that are not currently excepted, but it does not impact or restrict the exceptions currently provided for in the regulations.

(Comment 7) One comment recommends that the term ''embryos formed for autologous use'' not be used in conjunction with embryos. The commenter reasons that after a sperm or oocyte form an embryo, the embryo should not be considered autologous, given the definition at § 1271.3(a).

(Response) We agree with the comment and are not adopting, as part of the final rule, the term ''embryos formed for autologous use''. Likewise, we are not adopting, as part of the final rule, the reference to § 1271.90(a)(1) in § 1271.90(a)(4).

F. Labeling Requirements (§ 1271.370)

(Comment 8) Several comments were in support of labeling because it allows the physician to fully discuss the risks of any communicable disease and it allows the patient to make a fully informed decision. One commenter noted that factors affecting decisions of an HCT/P recipient may outweigh the expert advice of medical doctors. Another comment referenced § 1271.90(c)(6) of the proposed rule (embryo labeling requirements) that states establishments are required to ''advise recipients that screening and testing of the donor(s) were not performed at the time of recovery or cryopreservation of the reproductive cells or tissues, but have been performed subsequently.'' The comment further states that ''Description of the Proposed Rule'' provides that these labeling requirements are ''based on the expectation that a physician will be closely involved in the decision of the embryo and the recognition that physicians are under legal and ethical obligations that require them to discuss the risks of communicable disease transmission stemming from the use of HCT/Ps.'' The comment asked that FDA revise the rule to expressly require establishments to counsel recipients on the risk of disease.

(Response) We agree that the recipients should be fully informed about the risk of communicable disease before accepting an embryo for implantation; however, we decline to make the suggested change. As stated in the preamble of the proposed rule, the proposed labeling requirements are based on the expectation that a physician will be closely involved in the decision to use an embryo and the recognition that physicians are under legal and ethical obligations that require them to discuss the risks of communicable disease transmission stemming from the use of HCT/Ps. FDA relies on physicians to meet these obligations when discussing procedures involving HCT/Ps with recipients. Further, we expect that a recipient would be fully informed of the risks involved in using an embryo for reproductive purposes as finalized under § 1271.90(b) even when the donor eligibility requirements under part 1271, subpart C are not met.

(Comment 9) One comment suggested that while a labeling requirement that is tiered according to the risks may mitigate the risks, it does not go far enough in abolishing the risks.

(Response) As described under proposed § 1271.90(c)(2) through (6), an embryo originally intended for reproductive use for a specific individual or couple that is subsequently intended for directed or anonymous donation must be labeled as applicable. We acknowledge that the labeling requirement will not abolish all risks of implanting those embryos. Rather, as stated in the proposed rule, the required labeling would provide information to the treating physician to permit discussion of the potential risks of communicable diseases with the recipient. Our expectation is that the recipient will become fully informed of the risk when the donor eligibility requirements under part 1271, subpart C are not met, so that the recipient can make a well informed decision about receiving the embryo.

V. Effective Date

This rule is effective August 22, 2016.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have

developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs associated with this rule are expected to be minimal, we certify that the rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule amends certain regulations regarding donor eligibility and labeling related to the screening and testing of donors of particular HCT/Ps. The final rule will provide additional flexibility to HCT/P establishments to make available for reproductive use embryos originally intended for reproductive use for a specific individual or couple and subsequently intended for directed or anonymous donation. Specifically, the final rule will clarify that if an embryo was originally intended for reproductive use for a specific individual or couple, its use for directed or anonymous donation would not be prohibited under § 1271.45 (c), even when the applicable donor eligibility requirements under part 1271, subpart C are not met. This exception from prohibition for use would not create an exception for deficiencies that occurred in making the donor eligibility determination for either the oocyte donor or the semen donor as required under § 1271.45(b), or for deficiencies in performing donor screening or testing, as required under §§ 1271.75, 1271.80, and 1271,85. The final rule also requires appropriate labeling that describes the donor eligibility status of the individual donors whose gametes were used to form the embryo.

This rule will provide greater accommodation of individuals and couples wanting access to embryos originally intended for reproductive use for a specific individual or couple, while continuing to emphasize the applicability of the donor eligibility screening and testing requirements for individual gamete donors. The final rule will provide HCT/P establishments with the flexibility to make embryos originally intended for reproductive use for a specific individual or couple now available for directed or anonymous donation, provided that specific criteria are met. Consistent with current regulations, the labeling requirements will help ensure that physicians have specific and accurate information to provide to recipients for use in making informed medical decisions. Because this rule imposes no additional regulatory burdens, the costs associated with this rule are expected to be minimal.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

The labeling requirements contained in this final rule are not subject to review by the Office of Management and Budget (OMB) because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C 3501–3520). Rather, the requirement to label HCT/Ps in accordance with the final rule is a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)). Therefore, FDA concludes that these requirements in this document are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 1271

Biologics, Drugs, Human cells and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1271 is amended as follows:

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE–BASED PRODUCTS

■ 1. The authority citation for part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

■ 2. In § 1271.90:
■ a. Revise the heading;
■ b. Revise paragraph (a)(3) introductory text;
■ c. Revise paragraph (a)(4);
■ d. Redesignate paragraph (b) as paragraph (c);
■ e. Add a new paragraph (b);
■ f. Revise newly designated paragraph (c) introductory text;
■ g. Revise newly designated paragraph (c)(2); and
■ h. Revise newly designated paragraph (c)(6).

The revisions and additions read as follows:

§ 1271.90 Are there other exceptions and what labeling requirements apply?

(a) * * *

(3) Cryopreserved cells or tissue for reproductive use, other than embryos, originally excepted under paragraphs (a)(1) or (a)(2) of this section at the time of donation, that are subsequently intended for directed donation, provided that:

* * * * *

(4) A cryopreserved embryo, originally excepted under paragraph (a)(2) of this section at the time of recovery or cryopreservation, that is subsequently intended for directed or anonymous donation. When possible, appropriate measures should be taken to screen and test the semen and oocyte donors before transfer of the embryo to the recipient.

(b) *Exceptions for reproductive use.* An embryo originally intended for reproductive use for a specific individual or couple that is subsequently intended for directed or anonymous donation for reproductive use is excepted from the prohibition on

use under § 1271.45(c) even when the applicable donor eligibility requirements under subpart C of this part are not met. Nothing in this paragraph creates an exception for deficiencies that occurred in making the donor eligibility determination for either the oocyte donor or the semen donor as required under § 1271.45(b), or for deficiencies in performing donor screening or testing, as required under §§ 1271.75, 1271.80, and 1271.85.

(c) *Required labeling.* As applicable, you must prominently label an HCT/P described in paragraphs (a) and (b) of this section as follows:

* * * * *

(2) ''NOT EVALUATED FOR INFECTIOUS SUBSTANCES,'' unless you have performed all otherwise applicable screening and testing under §§ 1271.75, 1271.80, and 1271.85. This paragraph does not apply to reproductive cells or tissue labeled in accordance with paragraph (c)(6) of this section.

* * * * *

(6) ''Advise recipient that screening and testing of the donor(s) were not performed at the time of recovery or cryopreservation of the reproductive cells or tissue, but have been performed subsequently,'' for paragraphs (a)(3) or (a)(4) of this section.

§ 1271.370

■ 3. Amend § 1271.370(b)(4) by removing ''§ 1271.90(b)'' and by adding in its place ''§ 1271.90(c)''.

Dated: June 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14721 Filed 6–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9772]

RIN 1545–BN15

Modification of Treatment of Certain Health Organizations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance to Blue Cross and Blue Shield organizations, and certain other organizations, on computing and applying the medical loss ratio and the consequences for not meeting the medical loss ratio threshold. The final regulations reflect the enactment of a technical correction to section 833(c)(5) of the Internal Revenue Code by the Consolidated and Further Continuing Appropriations Act of 2015. The final regulations affect Blue Cross and Blue Shield organizations, and certain other organizations involved in providing health insurance.

DATES: *Effective Date:* These regulations are effective on June 22, 2016.

Applicability Date: For the date of applicability, see § 1.833–1(e).

FOR FUTHER INFORMATION CONTACT: Rebecca L. Baxter, at (202) 317–6995 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This Treasury decision contains final regulations that amend 26 CFR part 1 under section 833 of the Internal Revenue Code (the Code). Section 833(a) provides that Blue Cross and Blue Shield organizations, and certain other organizations involved in providing health insurance as described in section 833(c), are entitled to: (1) Treatment as stock insurance companies for purposes of sections 831 through 835 (related to taxation of non-life insurance companies generally); (2) a special deduction determined under section 833(b); and (3) computation of unearned premium reserves under section 832(b)(4) based on 100 percent, and not 80 percent, of unearned premiums for purposes of determining ''insurance company taxable income'' under section 832.

Section 833(c)(5) was added to the Code by section 9016 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119) (the Affordable Care Act), effective for taxable years beginning after December 31, 2009. Section 833(c)(5), as enacted by the Affordable Care Act, provided that section 833 did not apply to any organization unless the organization's medical loss ratio (MLR) for the taxable year was at least 85 percent. For purposes of section 833, an organization's MLR was its percentage of total premium revenue expended on reimbursement for clinical services provided to enrollees under its policies during such taxable year (as reported under section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18)).

Section 2718 of the Public Health Service Act (PHSA) was added by section 1001 and amended by section 10101 of the Affordable Care Act. Section 2718 of the PHSA is administered by the Department of Health and Human Services. Section 2718(a) of the PHSA requires a health insurance issuer to submit a report for each plan year to the Secretary of the Department of Health and Human Services concerning the percentage of total premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance, that the issuer expends: (1) On reimbursement for clinical services provided to enrollees under such coverage; (2) for activities that improve health care quality; and (3) on all other non-claims costs, excluding federal and state taxes and licensing or regulatory fees.

Section 2718(b) of the PHSA requires that a health insurance issuer offering group or individual health insurance coverage, with respect to each plan year, provide an annual rebate to each enrollee under such coverage, on a pro rata basis, if the ratio of the amount of the premium revenue the issuer expends on costs for reimbursement for clinical services provided to enrollees under such coverage and for activities that improve health care quality to the total amount of premium revenue (excluding federal and state taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Affordable Care Act (42 U.S.C. 18061, 18062, and 18063)) for the plan year is less than a prescribed percentage. Section 2718(b)(1)(B)(ii) of the PHSA provides that beginning on January 1, 2014, the medical loss ratio computed under section 2718(b) of the PHSA shall be based on expenses and premium revenues for each of the previous three years of the plan.

The Department of Health and Human Services published in the **Federal Register** (75 FR 74864) an interim final rule under section 2718 of the PHSA on December 1, 2010, an interim final rule and final rule on December 7, 2011 (76 FR 76596 and 76574), and a final rule on May 16, 2012 (77 FR 28790). These rules implementing section 2718 of the PHSA are codified at 45 CFR part 158 (HHS Regulations).

On December 6, 2010, the Treasury Department and the IRS published Notice 2010–79 (2010–49 I.R.B. 809), which provided interim guidance and transitional relief to organizations under section 833(c)(5). The interim guidance applied to an organization's first taxable year beginning after December 31, 2009.

The interim guidance provided that for purposes of determining whether an organization's percentage of total premium revenue expended on reimbursement for clinical services