

Observational Medical Outcomes Partnership (OMOP).

IMEDS's primary objective is to advance the science and tools necessary to support post-market evidence generation on regulated products, including safety surveillance and evaluations, and to facilitate utilization of a robust electronic healthcare data platform for generating better evidence on regulated products in the post-market settings. To accomplish this objective, the IMEDS program includes three projects:

1. IMEDS-Methods: Supports the development of a methods research agenda and coordination of methods research in support of using electronic health data for safety surveillance conducted by FDA as well as the broader community of researchers.
2. IMEDS-Education: Offers educational opportunities in areas related to medical product safety surveillance, and methods research and application for scientific professionals.
3. IMEDS-Evaluation: Applies Methods and Education lessons learned for medical product assessments to facilitate leveraging Sentinel tools and capabilities toward a national resource for evidence generation.

The IMEDS Steering Committee will have oversight of all IMEDS projects.

II. IMEDS Steering Committee Positions and Selection Criteria

RUF is seeking nominations for two (2) voting members of the IMEDS Steering Committee listed below.

1. At Large (excluding Pharmaceutical representative): 1 member.
 2. Provider (*i.e.*, Clinician): 1 member.
- The following criteria will be used to evaluate nominees for the IMEDS Steering Committee.

1. Required Criteria for Each of 2 Positions

a. Currently employed by/ volunteering for stakeholder field (*e.g.*, academia, patient advocate, provider etc.) with several years of relevant experience.

b. Leading expert in their relevant field (based on position/title, publications, or other experience).

2. Criteria across Steering Committee (*It is not a requirement that all nominees meet all of these criteria, but collectively, the Steering Committee members should meet them.*)

a. Ability to complete Steering Committee responsibilities (which can be accessed via the IMEDS Web site: <http://imeds.reaganudall.org/governance>.)

b. Prior experience serving on a related or similar governance body.

c. Understanding of post-market surveillance landscape and impact upon

stakeholder group represented by Steering Committee seat, or understanding of issues around use of electronic health data for observational purposes.

d. Individuals both with and without past experience in Mini-Sentinel, OMOP, and similar research/regulatory science initiatives to ensure a diversity of perspectives.

e. Individuals from both U.S.- and international-based institutions.

III. Terms of Service

- The IMEDS Steering Committee meets in-person at least twice per year, with bimonthly teleconferences in between meetings (or monthly teleconferences as deemed necessary by the Chair).

- Members serve two-year terms, and a maximum of two terms (based on IMEDS fiscal calendar).

- Members do not receive compensation from RUF.

- Members can be reimbursed by RUF for actual and reasonable expenses incurred in support of IMEDS in accordance with applicable law and their specific institutional policies.

- Members are subject to the IMEDS Conflict of Interest policies.

IV. Nomination Instructions

- To apply, please submit the nominee's CV and the nomination form that can be found on the IMEDS Web site: imeds.reaganudall.org, to IMEDS@reaganudall.org with "SC Nomination" in the subject line.

- Individuals may be nominated for one or more of the 2 voting positions, and those making nominations should specify for which of the 2 voting positions the nominee is being nominated.

- Individuals may nominate themselves.

Dated: May 4, 2015.

Jane Reese-Coulbourne,

Executive Director, Reagan-Udall Foundation for the FDA.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74863; File No. SR-NYSEArca-2015-01]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change Amending NYSE Arca Equities Rule 5.2(j)(3), Commentary .02 Relating to the Listing of Investment Company Units Based on Municipal Bond Indexes

May 4, 2015.

On January 16, 2015, NYSE Arca, Inc. ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend NYSE Arca Equities Rule 5.2(j)(3), Commentary .02 to accommodate the listing of certain Investment Company Units based on municipal bond indexes. The proposed rule change was published for comment in the **Federal Register** on February 4, 2015.³ On March 19, 2015, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ The Commission received no comment letters on the proposed rule change. This order institutes proceedings under Section 19(b)(2)(B) of the Act⁶ to determine whether to approve or disapprove the proposed rule change.

I. Description of the Exchange's Proposal⁷

NYSE Arca Equities Rule 5.2(j)(3) permits the listing and trading of Investment Company Units ("Units").⁸

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 74175 (Jan. 29, 2015), 80 FR 6150 ("Notice").

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 74534, 80 FR 15834 (Mar. 25, 2015). The Commission designated a longer period within which to take action on the proposed rule change and designated May 5, 2015, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ A complete description of the proposal can be found in the Notice. See Notice, *supra* note 3.

⁸ An "Investment Company Unit" is a security that represents an interest in a registered investment company that holds securities comprising, or otherwise based on or representing

Commentary .02 to NYSE Arca Equities Rule 5.2(j)(3) permits the listing and trading of a series of Units pursuant to Rule 19b-4(e) under the Act⁹ based on an underlying index or portfolio of “Fixed Income Securities”¹⁰ meeting specified criteria.¹¹ These “generic” listing criteria permit, without Commission approval pursuant to Section 19(b)(2) of the Act,¹² the listing and trading on the Exchange of a series of Units meeting such criteria.

Commentary .02(a)(2) to NYSE Arca Equities Rule 5.2(j)(3) provides that, to be listed and traded pursuant to Rule 19b-4(e) under the Act, components of an index or portfolio underlying a series of Units, in the aggregate, that account for at least 75% of the weight of the index or portfolio each shall have a minimum original principal amount outstanding of \$100 million or more. The Exchange proposes to amend this generic listing criterion to accommodate the listing of Units based on indexes or portfolios that include municipal bonds.¹³

Specifically, the Exchange proposes to amend NYSE Arca Equities Rule 5.2(j)(3), Commentary .02(a)(2) to state that components that, in the aggregate, account for at least 75% of the weight of an index or portfolio shall: (A) Each shall have a minimum original principal amount outstanding of \$100 million or more; or (B) if a municipal bond component, such component shall be issued in an offering with an aggregate size, as set forth in the offering’s official statement, of \$100 million or more. Accordingly, if an individual municipal

bond component of an index or portfolio has an amount outstanding of less than \$100 million, Units based on such an index or portfolio could still meet the generic listing standard if the municipal bond component were part of an overall municipal bond offering of \$100 million or more.

The Exchange provides that it is appropriate to calculate components of a municipal bond index differently from other Fixed Income Securities. Principally, the Exchange states that municipal bonds are issued with either “serial” or “term” maturities or some combination thereof. The official statement issued in connection with a municipal bond offering describes the terms of the component bonds and the issuer and/or obligor on the related bonds. Such an offering is comprised of a number of specific maturity sizes, but the entire issue or offering receives the same credit rating. Further, the entire issue or offering is based on a specified project or group of related projects and funded by the same revenue or other funding sources.

According to the Exchange, because the individual municipal bond components of an index or portfolio may predominantly have maturities of less than \$100 million outstanding (although part of a municipal bond offering of \$100 million or greater), if only individual maturity sizes are considered, Units based on a municipal bond index may not qualify to be listed under the generic listing standards. Accordingly, the Exchange believes the proposed amendment to Commentary .02(a)(2) would facilitate the listing of Units based on municipal bond indexes by permitting the Exchange, in applying its generic listing criteria, to take into account the aggregate size of the municipal bond offering.

The Exchange states that consideration of the aggregate size of the municipal bond offering, rather than the individual bond component, does not raise concerns regarding pricing or liquidity of the applicable municipal bond index components or of the Units overlying the applicable index. The Exchange states that, within a single municipal bond issuer, there are often multiple contemporaneous or sequential issuances that have the same credit rating, structure, and maturity. According to the Exchange, although these separate issues have different CUSIPs, because individual maturities share a number of important features, including credit rating and the purpose and terms of the offering as set forth in the applicable official statement, for investment purposes, they can be expected to be relatively fungible to one

another. Accordingly, the Exchange believes that the proposed rule change is reasonable and appropriate because the pricing and liquidity of such maturity sizes is predominately based on the common characteristics of the aggregate issue.

The Exchange also notes that major municipal bond indexes, while they include individual bond maturities as index components, include “deal size” as a factor in the criteria for index constituents and additions.¹⁴ Finally, the Exchange also provides that the Commission previously has approved the listing and trading of Units where the applicable municipal index components did not individually meet the 75% requirement of NYSE Arca Equities Rule 5.2(j)(3), Commentary .02(a)(2).¹⁵

II. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEArca–2015–01 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act¹⁶ to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,¹⁷ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be “designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,” and “to protect investors and the public interest.”¹⁸

¹⁴ In its proposal, the Exchange cites to the S&P National AMT-Free Municipal Bond Index, the Barclays Capital Investment-Grade Municipal Index, Barclays Capital High-Yield Municipal Index, and the Barclays Capital Enhanced State Specific Indices. See Notice, *supra* note 3, 80 FR at 6151.

¹⁵ See *supra* note 13.

¹⁶ 15 U.S.C. 78s(b)(2)(B).

¹⁷ *Id.*

¹⁸ 15 U.S.C. 78f(b)(5).

an interest in, an index or portfolio of securities (or holds securities in another registered investment company that holds securities comprising, or otherwise based on or representing an interest in, an index or portfolio of securities). See NYSE Arca Equities Rule 5.2(j)(3)(A).

⁹ See 17 CFR 240.19b-4(e).

¹⁰ “Fixed Income Securities” are described in NYSE Arca Equities Rule 5.2(j)(3), Commentary .02 as debt securities that are notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, U.S. Department of Treasury securities, government-sponsored entity securities, municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof.

¹¹ See Securities Exchange Act Release No. 55783 (May 17, 2007), 72 FR 29194 (May 24, 2007) (SR–NYSEArca–2007–36) (order approving generic listing standards for series of Units based on Fixed Income Indexes).

¹² 15 U.S.C. 78s(b)(2).

¹³ The Commission previously has approved proposed rule changes relating to listing and trading on the Exchange of Units based on municipal bond indexes. See, e.g., Securities Exchange Act Release No. 72523, (July 2, 2014), 79 FR 39016 (July 9, 2014) (SR–NYSEArca–2014–37) (order approving proposed rule change relating to the listing and trading of the iShares 2020 S&P AMT-Free Municipal Series under NYSE Arca Equities Rule 5.2(j)(3), Commentary .02). See also Notice, *supra* note 3, 80 FR at 6151, n.9.

III. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.¹⁹

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by May 29, 2015. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by June 12, 2015.

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice,²⁰ in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Exchange concludes that individual CUSIPs comprising the municipal bond offering can be expected to be relatively fungible to one another and that consideration of the aggregate size of the municipal bond offering, rather than the individual bond component, does not raise concerns regarding pricing or liquidity of the applicable municipal bond index components or of the Units overlying the applicable index. With respect to these conclusions, the Commission seeks comment on whether the generic listing criterion proposed to be amended would continue to serve to ensure that the underlying securities of these fixed income indexes are sufficiently liquid and price-transparent, and that, when applied in conjunction with the other

applicable generic listing requirements, would minimize potential manipulation.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2015-01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Numbers SR-NYSEArca-2015-01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of these filings also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2015-01 and should be submitted on or before May 29, 2015. Rebuttal comments should be submitted by June 12, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

Brent J. Fields,
Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74865; File No. SR-NYSEArca-2015-34]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the Fees for NYSE Arca Integrated Feed To Add a Late Fee In Connection With Failure To Submit the Non-Display Use Declaration

May 4, 2015.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Act") ² and Rule 19b-4 thereunder,³ notice is hereby given that, on April 24, 2015, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the fees for NYSE Arca Integrated Feed to add a late fee in connection with failure to submit the non-display use declaration, operative on May 1, 2015. The text of the proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at

¹⁹ Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94-29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

²⁰ See *supra* note 3.

²¹ 17 CFR 200.30-3(a)(57).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.