§ 1.98 Adjustment of civil monetary penalty amounts.

This section makes inflation adjustments in the dollar amounts of civil monetary penalties provided by law within the Commission's jurisdiction. The following maximum civil penalty amounts apply only to penalties assessed after January 17, 2025, including those penalties whose associated violation predated January 17, 2025.

(a) Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1)—$53,088;

(b) Section 11(*l*) of the Clayton Act, 15 U.S.C. 21(*l*)—$28,205;

(c) Section 5(*l*) of the FTC Act, 15 U.S.C. 45(*l*)—$53,088;

(d) Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. 45(m)(1)(A)—$53,088;

(e) Section 5(m)(1)(B) of the FTC Act, 15 U.S.C. 45(m)(1)(B)—$53,088;

(f) Section 10 of the FTC Act, 15 U.S.C. 50—$698;

(g) Section 5 of the Webb-Pomerene (Export Trade) Act, 15 U.S.C. 65—$698;

(h) Section 6(b) of the Wool Products Labeling Act, 15 U.S.C. 68d(b)—$698;

(i) Section 3(e) of the Fur Products Labeling Act, 15 U.S.C. 69a(e)—$698;

(j) Section 8(d)(2) of the Fur Products Labeling Act, 15 U.S.C. 69f(d)(2)—$698;

(k) Section 333(a) of the Energy Policy and Conservation Act, 42 U.S.C. 6303(a)—$575;

(l) Sections 525(a) and (b) of the Energy Policy and Conservation Act, 42 U.S.C. 6395(a) and (b), respectively—$28,205 and $53,088, respectively;

(m) Section 621(a)(2) of the Fair Credit Reporting Act, 15 U.S.C. 1681s(a)(2)—$4,983;

(n) Section 1115(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108–173, as amended by Public Law 115–263, 21 U.S.C. 355 note—$18,768;

(o) Section 814(a) of the Energy Independence and Security Act of 2007, 42 U.S.C. 17304—$1,510,803; and

(p) Civil monetary penalties authorized by reference to the Federal Trade Commission Act under any other provision of law within the jurisdiction of the Commission—refer to the amounts set forth in paragraphs (c), (d), (e) and (f) of this section, as applicable.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2025–01361 Filed 1–16–25; 8:45 am]

BILLING CODE 6750–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA–2024–0056]

RIN 0960–AI93

Further Extension of the Flexibility in Evaluating ''Close Proximity of Time'' To Evaluate Ongoing Changes in Healthcare

AGENCY: Social Security Administration.

ACTION: Temporary final rule with request for comments.

SUMMARY: We are extending the flexibility in the ''close proximity of time'' standard, as defined in two prior temporary final rules (TFR), through May 11, 2029. We issued a TFR providing the ''close proximity of time'' flexibility on July 23, 2021, because the COVID–19 national public health emergency (PHE) caused many individuals to experience barriers that prevented them from timely accessing in-person healthcare. On September 29, 2023, we extended the flexibility to evaluate evolving healthcare practices and consumption in a post-PHE environment. We determined that we need additional time to fully evaluate still-evolving healthcare practices after the PHE. We are therefore issuing this TFR to extend the ''close proximity of time'' flexibility until May 11, 2029, so we can continue to evaluate changes in healthcare practices and determine the proper ''close proximity of time'' standard for the musculoskeletal disorders listings.

DATES:

Effective date: This TFR is effective on February 18, 2025.

Comment date: We invite written comments. Comments must be submitted no later than March 18, 2025.

Expiration date: Unless we extend the provisions of this TFR by a final rule published in the **Federal Register**, it will cease to be effective on May 11, 2029.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comment(s) multiple times or by more than one method. Regardless of which method you choose, please state that your comment(s) refer to Docket No. SSA–2024–0056 so that we may associate your comment(s) with the correct rule.

Caution: You should be careful to include in your comment(s) only information that you wish to make publicly available. We strongly urge you not to include any personal information in your comment(s), such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comment(s) via the internet. Please visit the Federal eRulemaking portal at *https://www.regulations.gov.* Use the ''search'' function to find docket number SSA–2024–0056. The system will issue a tracking number to confirm your submission. You will not be able to view your comment(s) immediately because we must post each comment manually. It may take up to one week for your comment(s) to be viewable.

2. *Fax:* Fax comments to 1–833–410–1631.

3. *Mail:* Mail your comments to the Office of Legislation and Congressional Affairs Regulations and Reports Clearance Staff, Mail Stop 3253, Altmeyer, 6401 Security Blvd., Baltimore, MD 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *https://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Michael J. Goldstein, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–1020.

For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *https://www.ssa.gov/.*

Background

On December 3, 2020, we published the final rule, *Revised Medical Criteria for Evaluating Musculoskeletal Disorders* (final rule),[1] which became effective on April 2, 2021. This final rule revised the criteria in the listings that we use to evaluate disability claims involving musculoskeletal disorders in adults and children at the third step of our sequential evaluation process under titles II and XVI of the Social Security Act (Act).[2] The final rule, among other

[1] 85 FR 78164 (2020).

[2] For adults, the listings describe, for each of the major body systems, impairments that we consider to be severe enough to prevent an individual from doing any gainful activity regardless of his or her age, education, or work experience. 20 CFR 404.1525(a) and 416.925(a). For children, the listings describe impairments we consider severe enough to cause marked and severe functional limitations. 20 CFR 416.925(a). We use the listings at step 3 of the sequential evaluation process to identify claims in which the individual is clearly disabled under our rules. 20 CFR 404.1520, 416.920, and 416.924). We do not deny a claim when a person's medical impairment(s) does not satisfy the criteria of a listing. Instead, we continue

things, revised the listings in response to the decision in *Radford* v. *Colvin,*[3] which interpreted former listing 1.04A to require a disability claimant to show only ''that each of the symptoms are present, and that the claimant has suffered or can be expected to suffer from [the condition] continuously for at least 12 months.'' [4] Under the court's interpretation of the former listing, a claimant did not need to show that each necessary criterion was present simultaneously or in particularly close proximity, as required by our interpretation of that listing.[5] The final rule clarified that, for the purposes of applying certain musculoskeletal disorders listings,[6] all of the required medical criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed for the impairment to meet the listing. The final rule further defined the phrase ''within a close proximity of time'' to mean ''that *all* of the relevant criteria must appear in the medical record within a consecutive 4-month period'' (emphasis in original).[7] We also provided that ''[w]hen the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset.'' [8]

We established the consecutive 4-month period as a criterion to meet the level of severity in some of the musculoskeletal disorders listings based on our research of then relevant medical literature and clinical guidelines.[9] When we proposed this requirement as part of a notice of proposed rulemaking (NPRM),[10] we specifically asked interested members of the public to comment on this issue and provide us with any studies and data that supported their comments for a different standard.[11] In response, a number of commenters raised concerns regarding barriers to accessing medical providers or documenting medical listing criterion.[12] However, none of the commenters submitted studies or data. In the final rule, we concluded that the consecutive 4-month period was consistent with the timeframe medical providers were generally trained to use for scheduling their patients,[13] the general standard of care,[14] and the frequency of healthcare visits by individuals with musculoskeletal conditions.[15] At the same time, the consecutive 4-month period provided some leeway for claimants, because the standard for patient revisits was once every 3 months.[16]

Onset of COVID–19

In 2020, the COVID–19 virus began to spread throughout the country, prompting the Secretary of Health and Human Services (HHS) to declare a national PHE on January 31, 2020.[17] With the outbreak of COVID–19, access to and the provision of healthcare changed significantly. Throughout the PHE, individuals across the country—including those with musculoskeletal disorders—altered their frequency and manner of seeking access to healthcare. This was due in part to healthcare organizations and government agencies such as the Centers for Medicare & Medicaid Services (CMS) [18] prioritizing the most urgent services and encouraging patients to delay other procedures during the PHE. Likewise, many individuals delayed or deferred important treatments due to closures of medical offices, fears of contracting COVID–19 infection (including fear of exposing high-risk individuals living in their household to infection), and other challenges created or exacerbated by the pandemic, such as difficulty accessing transportation.

In July 2021, we published a TFR entitled *Flexibility in Evaluating ''Close Proximity of Time'' Due to COVID–19 Related Barriers to Healthcare* [19] (2021 TFR). We acknowledged at that time that the response to the COVID–19 pandemic dramatically changed the provision of, and access to, healthcare services throughout the country, and we cited evidence showing that significant numbers of people had foregone or delayed care, or replaced in-person medical visits with telehealth visits.[20] Therefore, we concluded that individuals with musculoskeletal impairments who, before the pandemic, would have sought and received healthcare at a frequency consistent with the standards in our final rule, might have become unable to seek, or might have chosen not to seek, care for their condition in the same manner and frequency. Affected individuals whose impairments might have previously met the applicable listing requirements might have subsequently failed to meet the ''close proximity of time'' standard because of the changes in the provision of healthcare resulting from COVID–19. We therefore extended the timeframe for an individual's record to demonstrate the necessary listing criteria throughout the pandemic period.

The 2021 TFR defined the ''pandemic period'' for the purposes of our regulations and provided that during the ''pandemic period,'' the phrase ''within a close proximity of time'' meant that *all* of the relevant criteria must appear in the medical record within a consecutive 12-month period.'' [21] We further defined the ''pandemic period'' as beginning on April 2, 2021 and ending 6 months after the Secretary of HHS determined that the COVID–19 national PHE no longer existed. We extended the ''pandemic period'' for 6 months after the end of the COVID–19 national PHE to allow time for healthcare access and provision to normalize and return to pre-pandemic period levels as well as to account for potential backlogs in medical care that may have continued to interfere with

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the sequential evaluation process. 20 CFR 404.1520(a)(4) and 416.920(a)(4).

[3] *Radford* v. *Colvin,* 734 F.3d 288 (4th Cir. 2013).

[4] Id. at 294.

[5] See Acquiescence Ruling 15–1(4). We rescinded that Acquiescence Ruling after we revised the listings in 2020. 85 FR 79063 (2020).

[6] Listings 1.15, 1.16, 1.17, 1.18, 1.20C, 1.20D, 1.22, 1.23, 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23.

[7] See 85 FR 78164 (2020) (revising 20 CFR part 404, subpart P, Appendix 1, 1.00C7c and 101.00C7c).

[8] Id.

[9] See 85 FR at 78169–78170.

[10] 83 FR 20646 (2018).

[11] Id. at 20647.

[12] See, *e.g.,* comment from Community Legal Services of Philadelphia on Document SSA–2006–0112–0010, *https://www.regulations.gov/comment/SSA-2006-0112-0046.*

[13] 85 FR at 78169 n.37 (citing Bavafa, H., Savin, S., & Terwiesch, C. (2019). Redesigning Primary Care Delivery: Customized Office Revisit Intervals and E-Visits. *https://dx.doi.org/10.2139/ssrn.2363685.* Paper referenced by Bavafa: Schectman, G., G. Barnas, P. Laud, L. Cantwell, M. Horton, E.J. Zarling. 2005. Prolonging the return visit interval in primary care. The American Journal of Medicine, 118(4) 393–399).

[14] 85 FR at 78169 n.34 (citing Gore, M., Sadosky, A., Stacey, B.R., Tai, K.S., & Leslie, D. (2012). The burden of chronic low back pain: Clinical comorbidities, treatment patterns, and health care costs in usual care settings. Spine, 37(11), E668–E677. *https://doi.org/10.1097/BRS.0b013e318241e5de*).

[15] 85 FR at 78169 n.35 (citing BMUS: The Burden of Musculoskeletal Diseases in the United States. In: BMUS: The Burden of Musculoskeletal Diseases in the United States [internet]. [cited 15 July 2020]. *https://www.boneandjointburden.org/fourth-edition/viiic2/utilization-condition-group*).

[16] See 85 FR at 78169 n.36 (citing J Gen Intern Med. 1999 Apr; 14(4): 230–235. doi: 10.1046/j.1525–1497.1999.00322.x Lisa M Schwartz, MD, MS, Steven Woloshin, MD, MS, John H Wasson, MD, Roger A Renfrew, MD, and H Gilbert Welch, MD, MPH, Dartmouth Primary Care Cooperative Research Network).

[17] Determination That A Public Health Emergency Exists by Alex M. Azar II, *Secretary of Health & Human Services* (Jan. 31. 2020) (*https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx).*

[18] Centers for Medicare & Medicaid Services (CMS) Recommendations: Re-opening Facilities to Provide Non-emergent Non-COVID–19 Healthcare (*https://www.cms.gov/files/document/covid-recommendations-reopening-facilities-provide-non-emergent-care.pdf*); see also Non-Emergent, Elective Medical Services, and Treatment Recommendations (*https://www.cms.gov/files/document/cms-non-emergent-elective-medical-recommendations.pdf*).

[19] 86 FR 38920 (2021).

[20] Id.

[21] 86 FR at 38925.

access to the relevant care and documentation needed to satisfy the listing criteria. We also indicated that we would study the application of ''close proximity of time'' flexibility on our programs.[22]

When we published the 2021 TFR in the **Federal Register**, we provided the public with a 60-day comment period, which ended on September 21, 2021. We specifically contemplated the possibility of extending the flexibility and we invited comments on all aspects of the rule, including the definition of ''pandemic period'' and the expiration date. We received one comment from the National Organization of Social Security Claimants' Representatives (NOSSCR) [23] that encouraged us to make the temporary 12-month standard permanent. The commenter also recommended, if we chose not to make the 12-month standard permanent, that we extend the period to one year after the end of the PHE. They argued that access to care issues exist regardless of the pandemic and that it would take longer than 6 months for healthcare delivery to normalize after the end of the PHE.

Issuance of the 2023 TFR Extending the 12-Month Standard

The 2021 TFR was effective until six months after the effective date of a determination by the Secretary of HHS that a PHE resulting from the COVID–19 pandemic ended. The Secretary of HHS made that determination on May 11, 2023.[24] Consequently, the 2021 TFR was set to expire in November 2023.

On September 29, 2023, we extended the ''close proximity of time'' flexibility through May 11, 2025.[25] We explained at the time that we intended the extension to allow for time to study changes in healthcare access and provision, and to account for the ongoing increased use of telehealth services following the PHE. We further explained that we would continue to evaluate these evolving practices and their effects to determine the appropriate ''close proximity of time'' standard to include in the musculoskeletal disorders listings going forward.[26]

In issuing the extension, we also discussed the public comment we received from NOSSCR about the 2021 TFR, encouraging us to make the 12-month standard permanent or extend it to apply for one year after the end of the PHE. We explained that by May 2025, we expected to determine whether we should extend the TFR again, make the flexibility in the TFR permanent, as the commenter recommended, propose a different standard, or let the TFR expire and revert to the 4-month ''close proximity of time'' standard. Additionally, we noted that while the commenter raised issues regarding general barriers to accessing care that disability benefit applicants may be disproportionally likely to experience, we considered the comment outside the scope of the second TFR and committed to addressing these comments in a future venue.

Public Comment on the 2023 TFR

When we extended the flexibility again in 2023, we received one comment, from The Connected Health Initiative. The commenter was supportive of us extending the flexibility provided in the TFR and our commitment to continuing to study the appropriate time period for ''close proximity of findings,'' noting that ''data indicates that, going forward, telehealth will likely replace some in-person visits for some people with musculoskeletal disorders post-PHE, which could lead to extended revisit intervals between thorough examinations.'' [27] We appreciate this commenter's feedback and, consistent with the comment, intend to continue studying these impacts.

Rationale for This Rule

We are extending the ''close proximity of time'' flexibility through May 11, 2029, to allow for additional time to study changes in healthcare access and provision, and to account for the ongoing increased use of telehealth services following the PHE. We will evaluate these evolving practices and their effects to determine the appropriate time standard to include in the musculoskeletal disorders listings going forward.

The PHE caused changes in healthcare provision and access, which led to a decrease in health care use and a shift from in-person healthcare to telehealth (phone or video). In response, we published the 2021 TFR, which temporarily amended the introductory text of the musculoskeletal disorders listings to define the ''close proximity of time'' standard as presence of the required findings in the record within a consecutive 12-month period. This flexibility was limited to the ''pandemic period,'' originally defined as the period beginning April 2, 2021, until 6 months after the end of the COVID–19 national PHE, November 11, 2023. Due to the ongoing increased use of telehealth services following the PHE and the many changes to healthcare rules and legislation that were set to be phased out over a two-year period, we concluded that healthcare would be in a state of rapid change in the period immediately following the PHE, so we would need to study the changes in healthcare provision before defining the appropriate ''close proximity of time'' interval going forward. We thus published an extension of the flexibility provided in the TFR by redefining the ''pandemic period'' to end on May 11, 2025, two years after the end of the PHE.

After studying the available data regarding the changes in healthcare immediately following the PHE, we have concluded that a further extension is necessary because healthcare access and provision remains different from what it was prior to the PHE and we are continuing to evaluate whether the 4-month period is supported. There is still uncertainty and change in the medical and legal framework regarding telehealth, and the limited data available about telehealth use immediately after the PHE shows ongoing increased telehealth use compared to the period prior to the PHE. For example, Medicare data shows that telehealth usage across all medical specialties increased significantly during the pandemic, and while telehealth usage gradually declined from its peak, it has not returned to pre-pandemic levels.[28]

Telehealth examinations may provide continuity of care, but they generally cannot provide all the medical findings required under the musculoskeletal disorders listings. Additionally, anecdotal evidence from after the PHE suggests that healthcare costs and workforce shortages, which were exacerbated by the pandemic, have led

[22] 86 FR at 38924.

[23] See Comment from National Organization of Social Security Claimants' Representatives on Document SSA–2021–0010–0001, *https://www.regulations.gov/comment/SSA-2021-0010-0002.*

[24] Becarra, X. (2023, May 11). Statement on End of the COVID–19 Public Health Emergency. *Department of Health and Human Services. https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.*

[25] 88 FR 67081 (2023).

[26] 88 FR 67082.

[27] See Comment from The Connected Health Initiative on Document SSA–2023–0023–0002, *https://www.regulations.gov/comment/SSA-2023-0023-0002.*

[28] Centers for Medicare & Medicaid Services (2024, July). *Medicare Telehealth Trends Report.* Centers for Medicare and Medicaid Services, U.S. Department of Health & Human Services (HHS). *.https://data.cms.gov/sites/default/files/2024-09/c213a5e9-9e70-4b46-b5f1-2fb941ea0f6c/Medicare%20Telehealth%20Trends%20Snapshot%2020240827_508.pdf.*

to deferment of care and long wait times to see providers. These issues are projected to get worse over the next decade,[29] which could result in further delays in accessing in-person examinations, which provide the evidence we need to evaluate musculoskeletal disorders. We need further data to establish a permanent definition for ''close proximity of time.''

Available research and data on post-PHE healthcare provides an uncertain picture of the long-term impact of the COVID–19 pandemic. Although the PHE ended on May 11, 2023, several flexibilities provided during the PHE to increase telehealth access have been extended through March 31, 2025 (*e.g.,* Medicare coverage of audio-only telehealth, telehealth originating at a patient's home, and telerehabilitation).[30] Additionally, Congress is considering permanent changes to provide additional flexibilities for telehealth.[31] In addition to the evolving nature of telehealth, there are also significant delays in care provision due to healthcare workforce shortages and access issues that have persisted and, in many cases, worsened after the PHE.

Although the research is still developing and most professional organizations still have yet to update their clinical practice guidelines for post-pandemic healthcare, the emerging research and data suggest that the increased use of telehealth (including in place of some in-person visits) is generally appreciated by patients and providers and expected to continue for some time, but at a lower level than at the height of the pandemic.[32] This appears true for both audio-only and audio-visual telehealth modalities, and for specialties that previously only sparingly used telehealth, such as orthopedic surgery, spine surgery, and rehabilitation.[33] In the field of rehabilitation, the American Physical Therapy Association recently published clinical practice guidelines supporting telerehabilitation as a mode of delivering physical therapist services to patients who would benefit from services and whose barriers can be accommodated. At the same time, they noted that additional telerehabilitation research is needed for all ages, digital health applications, physical therapist measures, and interventions.[34] Nevertheless, there is a yearslong research lag that limits availability of post-PHE data, making it difficult to fully quantify the post-PHE utilization of telehealth and in-person care in practice.[35]

The initial data from CMS and the Department of Veterans Affairs (VA) appears to show that rates of telehealth use for the first few months after the end of the PHE remained steady and generally consistent with utilization rates in late 2021 and 2022.[36] VA data showed an overall increase in the proportion of telehealth visits from 20 percent prior to the pandemic to about 35 percent leading up to and for the first few months after the end of the PHE. Researchers analyzing the VA data through August 2023 indicated that telehealth rates stabilized around May 2021 and that ''although primary care and subspecialty telemedicine is often limited by the need for in-person evaluations (for example, physical examinations), about 10% of in-person primary and subspecialty care has converted to telemedicine.'' [37] Additionally, Medicare data trends through the second quarter of 2024 showed rates of telehealth stabilizing between 12 and 15 percent of Medicare users in 2022 through June 2024, compared to 7 percent of users prior to the pandemic. They also showed differences in telehealth use by race, ethnicity, age, disability status, and dual enrollment status with Medicaid. The data shows that Medicare users who were disabled or who were dually eligible for Medicare and Medicaid tended to use telehealth more both during and after the PHE.[38]

Anecdotal evidence supports that telehealth is still being used at higher rates than prior to the pandemic, but that additional research is needed to describe the role of telehealth in healthcare after the PHE. At their presentation to the National Academies of Science, Engineering, and Medicine (NASEM) Standing Committee of Medical and Vocational Experts for the Social Security Administration's Disability Programs, two experts in musculoskeletal care affirmed that although telehealth is more common now than prior to the pandemic and provides benefits for those who use it, there is no currently available data that provides a picture of telehealth use following the PHE. They concluded that there is not an industry standard for telehealth utilization at this time, with more research, consensus, and standardization needed in the field.[39]

[29] *See, e.g.,* Blumenthal, D., Gumas, E., & Shah, A. (2024). The Failing U.S. Health System. *The New England journal of medicine, 391*(17), 1566–1568. *https://doi.org/10.1056/NEJMp2410855,* and GlobalData Plc. (2024, March) *The Complexities of Physician Supply and Demand: Projections From 2021 to 2036.* AAMC; *https://www.aamc.org/media/75236/download?attachment.*

[30] HHS (2023, May 10). *HHS Fact Sheet: Telehealth Flexibilities and Resources and the COVID–19 Public Health Emergency.* HHS *https://www.hhs.gov/about/news/2023/05/10/hhs-fact-sheet-telehealth-flexibilities-resources-covid-19-public-health-emergency.html; see also* American Physical Therapy Association (2023, May) *Three Years of Physical Therapy in a Public Health Emergency: the Impact of the COVID–19 Pandemic on the Physical Therapy Profession.* APTA and The American Relief Act of 2025, Public Law 118–158. BILLS–118hr10545eh.pdf. *https://www.apta.org/contentassets/143242e710e147cfa30c0405f5c8ef64/apta_covid19_report2023.pdf.*

[31] Cottrill, A. & Cubanski, J. & Neuman, T., (2024, October 2). *What to Know about Medicare Coverage of Telehealth.* The Kaiser Family Foundation. *https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-coverage-of-telehealth/.*

[32] Shaver J. (2022). The State of Telehealth Before and After the COVID–19 Pandemic. *Primary care, 49*(4), 517–530. *https://doi.org/10.1016/j.pop.2022.04.002.*

[33] Bartelt, K., Piff, A., Allen, S., & Barkley, E. (2023, November 21). *Telehealth Utilization Higher Than Pre-Pandemic Levels, but Down from Pandemic Highs.* Epic Research. *https://epicresearch.org/articles/telehealth-utilization-higher-than-pre-pandemic-levels-but-down-from-pandemic-highs.* Accessed on November 27, 2024.

[34] Lee, A.C., Deutsch, J.E., Holdsworth, L., Kaplan, S.L., Kosakowski, H., Latz, R., McNeary, L.L., O'Neil, J., Ronzio, O., Sanders, K., Sigmund-Gaines, M., Wiley, M., & Russell, T. (2024). Telerehabilitation in Physical Therapist Practice: A Clinical Practice Guideline From the American Physical Therapy Association. *Physical therapy, 104*(5), pzae045. *https://doi.org/10.1093/ptj/pzae045.*

[35] Standaert, Christopher, M.D. COVID Disruptions and their Impact on Musculoskeletal Care. Presentation to the Standing Committee of the National Academies of Science and Medicine Health and Medicine Division, on June 20, 2024.

[36] Ferguson, J.M., Wray, C.M., Van Campen, J., & Zulman, D.M. (2024). A New Equilibrium for Telemedicine: Prevalence of In-Person, Video-Based, and Telephone-Based Care in the Veterans Health Administration, 2019–2023. *Annals of internal medicine, 177*(2), 262–264. *https://doi.org/10.7326/M23-2644; see also* Centers for Medicare & Medicaid Services (2022, December). *Medicare Telehealth Trends Report.* Centers for Medicare & Medicaid Services, HHS. *https://data.cms.gov/sites/default/files/2022-12/a7c3a319-5ded-4baf-ad7c-9aa2a897263a/MedicareTelehealthTrends Snapshot20221201.pdf.*

[37] Ferguson, J.M., Wray, C.M., Van Campen, J., & Zulman, D.M. (2024). A New Equilibrium for Telemedicine: Prevalence of In-Person, Video-Based, and Telephone-Based Care in the Veterans Health Administration, 2019–2023. *Annals of internal medicine, 177*(2), 262–264. *https://doi.org/10.7326/M23-2644.*

[38] Centers for Medicare & Medicaid Services (2024, November). Medicare Telehealth Trends Report. *Centers for Medicare & Medicaid Services, HHS https://data.cms.gov/sites/default/files/2024-12/f5b35fbf-002a-425d-924d-f99aa362a63f/Medicare%20Telehealth%20Trends%20Snapshot%2020241127_508.pdf; see also* Centers for Medicare & Medicaid Services (2024, May). Medicare Telehealth Trends Report. *Centers for Medicare & Medicaid Services, HHS https://data.cms.gov/sites/default/files/2024-05/Medicare%20Telehealth%20Trends%20Snapshot%2020240528_508.pdf.*

[39] Standaert, Christopher, M.D. COVID Disruptions and their Impact on Musculoskeletal Care. Presentation to the Standing Committee of the National Academies of Science and Medicine Health and Medicine Division, on June 20, 2024; *see also* Escorpizo, Reuben, P.T., M.Sc., D.P.T. Musculoskeletal Health, and Telehealth—Rapid Overview. Presentation to the Standing Committee

Continued

The conclusions of the experts are supported by a report from the Outcomes Planning Committee of the VHA Office of Health Services Research and Development's State-of-the-Art Conference on Virtual Care. The report concluded that there is a need for additional research to identify the specific scenarios in which virtual care can be leveraged to improve patient outcomes, and that additional research regarding the use of hybrid models ''will be critical in determining whether virtual visits should function primarily as periodic check-ins before patients can receive certain examinations or procedures in-person, or whether virtual care can fully replace in-person care in specific clinical scenarios.'' [40]

Although many individuals access telehealth visits successfully, the clinical signs and findings required by some of the musculoskeletal disorders listings may not be present in the telehealth record due to the limitations of telemedicine. While testing by the patient is possible through telehealth, there are limits in provocative testing (testing that manipulates the areas where an individual has pain in order to reproduce the pain), discrete palpation (a technique that uses targeted pressure to identify and quantify the abnormalities of the musculoskeletal system, such as warmth, swelling, pain, tenderness, and trigger points), and strength or stability testing.[41] During the beginning of the COVID–19 pandemic, orthopedists created guidelines for virtual examinations of patients through telemedicine, and found that while the patient could perform many tests, there are inherent limitations to testing in this manner. For example, the authors recommend using another person to hold the camera during gait examination to get a better view of the patient's gait mechanics, which is not always possible.[42] Further, the VHA has found that although patients appreciate telehealth, many are unable to complete exams that require precise measurements, such as range of motion or reflexes.[43] While it appears that since the end of the PHE there have been some post-surgical innovations to conduct follow-up spine care virtually, such as applications that can be used on a smartphone,[44] a recent survey of orthopedic trauma care providers shows that concerns still exist about the generalizability of telemedicine to the field of orthopedic trauma care, as a majority of orthopedic physicians felt that virtual physical examinations allowed for only limited information.[45] Thus, the utility of telehealth examination in the specific context of surgical and/or orthopedic trauma care remains uncertain.

Additionally, an increasing number of people are unable to access needed healthcare due to cost as the PHE flexibilities are phased out. Medicaid redeterminations restarted at the end of the PHE, leading to an increase in the uninsured, and the enhanced health insurance marketplace subsidies will expire in 2025.[46] According to data from the Kaiser Family Foundation (KFF), over 25 million people have been disenrolled from Medicaid since April 2023, when the ''unwinding'' of the continuous enrollment provision began, leading to an increase in the uninsured population.[47]

The Congressional Budget Office predicts an increase in the share and number of people without insurance over the next decade, with a predicted increase in the uninsured population from 24 million in 2023 to 32 million in 2027, primarily driven by changes in Medicaid and Children's Health Insurance Program (CHIP) enrollment over the next few years resulting from the expiration of PHE-era programs.[48] National surveys from KFF and the Federal Reserve in 2022 and 2023 showed that a large percentage of people (25 to 28 percent) postponed or went without needed medical care due to cost regardless of insurance status, and that the uninsured population was significantly more likely to forego or postpone care (42 to 60 percent) than the insured population.[49]

The Commonwealth Fund's 2024 report, which compared the performance of health systems of 10 high-income countries using data from 2020 or later and is the first such report to account for the effects of the COVID–19 pandemic, found that the United States ranked last on several measures, including access to care, and this was attributed largely to cost-related barriers, such as the percentage of uninsured residents as well as inadequate coverage and high deductibles and copayments.[50] The Commonwealth Fund's 2023 survey noted that nearly half of adults with lower or average incomes in the U.S., and nearly one of three with higher incomes, reported at least one cost-related problem accessing health care in the prior year. The problems included

of the National Academies of Science and Medicine Health and Medicine Division, on June 20, 2024.

[40] Connolly, S.L., Sherman, S.E., Dardashti, N., Duran, E., Bosworth, H.B., Charness, M.E., Newton, T.J., Reddy, A., Wong, E.S., Zullig, L.L., & Gutierrez, J. (2024). Defining and Improving Outcomes Measurement for Virtual Care: Report from the VHA State-of-the-Art Conference on Virtual Care. *Journal of general internal medicine, 39*(Suppl 1), 29–35. *https://doi.org/10.1007/s11606-023-08464-1.*

[41] Tanaka, M.J., Oh, L.S., Martin, S.D., & Berkson, E.M. (2020). Telemedicine in the Era of COVID–19: The Virtual Orthopaedic Examination. *The Journal of Bone and Joint Surgery, American volume, 102*(12), e57. *http://dx.doi.org/10.2106/JBJS.20.00609.*

[42] Laskowski, E.R., Johnson, S.E., Shelerud, R.A., Lee, J.A., Rabatin, A.E., Driscoll, S.W., Moore, B.J., Wainberg, M.C., & Terzic, C.M. (2020). The Telemedicine Musculoskeletal Examination. *Mayo Clinic Proc.* 95(8). doi: *https://doi.org/10.1016/j.mayocp.2020.05.026.*

[43] Baus, Shanna, PA–C. Telehealth & Disability Items: Veterans Health Administration. Presentation to the Standing Committee of the National Academies of Science and Medicine Health and Medicine Division, on December 1, 2020; *see also* Cannedy, S., Leung, L., Wyte-Lake, T., Balut, M.D., Dobalian, A., Heyworth, L., Paige, N.M., & Der-Martirosian, C. (2023). Primary Care Team Perspectives on the Suitability of Telehealth Modality (Phone vs Video) at the Veterans Health Administration. *Journal of primary care & community health, 14,* 21501319231172897. *https://doi.org/10.1177/21501319231172897.*

[44] Leyendecker, J., Prasse, T., Bieler, E., Yap, N., Eysel, P., Bredow, J., Hofstetter, C.P., & Members of the Endoscopic Spine Research Group (ESRG) (2024). Smartphone applications for remote patient monitoring reduces clinic utilization after full-endoscopic spine surgery. *Journal of telemedicine and telecare,* 1357633X241229466. Advance online publication. *https://doi.org/10.1177/1357633X241229466.; see also* Murhekar, S., Relwani, S., Lau, S., & Virani, S. (2024). Evaluation of the Effectiveness of Virtual Telephone Consultations Against Traditional Face-to-Face Consultations in Spine Surgery Using an Objective Metric. *Cureus, 16*(9), e69433. *https://doi.org/10.7759/cureus.69433.*

[45] Gammel, J., Rivas, G., Horn, R., Munford, J., Reid, K., & Harstock, L. (2024, September 4). A survey of telehealth and its role in orthopaedic trauma during and after COVID–19. *Journal of Public Health (Berl.) https://doi.org/10.1007/s10389-024-02347-3.*

[46] Tolbert, J., & Corallo, B. (2024, September 18). *An examination of Medicaid Renewal Outcomes and enrollment changes at the end of the Unwinding.* The Kaiser Family Foundation. *https://www.kff.org/medicaid/issue-brief/an-examination-of-medicaid-renewal-outcomes-and-enrollment-changes-at-the-end-of-the-unwinding/; See also* Minicozzi, A., & Masi, S. (2024, June 18). CBO Publishes New Projections Related to Health Insurance for 2024 to 2034, CBO. *https://www.cbo.gov/publication/60383.*

[47] Tolbert, J., & Corallo, B. (2024, September 18). *An examination of Medicaid Renewal Outcomes and enrollment changes at the end of the Unwinding.* The Kaiser Family Foundation. *https://www.kff.org/medicaid/issue-brief/an-examination-of-medicaid-renewal-outcomes-and-enrollment-changes-at-the-end-of-the-unwinding/.*

[48] Hale, J., Hong, N., Hopkins, B., Lyons, S., Molloy, E., & The Congressional Budget Office Coverage Team (2024). Health Insurance Coverage Projections for the US Population and Sources Of Coverage, By Age, 2024–34. *Health affairs (Project Hope), 43*(7), 922–932. *https://doi.org/10.1377/hlthaff.2024.00460.*

[49] Tolbert, J., & Corallo, B. (2024, September 18). *An examination of Medicaid Renewal Outcomes and enrollment changes at the end of the Unwinding.* The Kaiser Family Foundation. *https://www.kff.org/medicaid/issue-brief/an-examination-of-medicaid-renewal-outcomes-and-enrollment-changes-at-the-end-of-the-unwinding/.*

[50] Blumenthal, D., Gumas, E., & Shah, A. (2024). The Failing U.S. Health System. *The New England journal of medicine, 391*(17), 1566–1568. *https://doi.org/10.1056/NEJMp2410855.*

having a medical issue but not visiting a doctor, skipping a medical test, treatment, or follow-up that was recommended by a doctor, not filling a prescription, or skipping medication doses.[51] Given the projected increases in the uninsured population and the impact of cost and insurance status on access to care, postponed and foregone health care is expected to remain an issue for the foreseeable future, potentially limiting the frequency of visits.

Additional research suggests that certain individuals, such as those who are uninsured or low-income, may face barriers to regular or recommended health care treatment, and that these barriers appear to have increased after the pandemic, which may warrant a longer standard to allow for developing the necessary evidence. In a separate publication, summarizing recent research, KFF notes that studies repeatedly demonstrate that uninsured individuals are less likely than those with insurance to receive preventive care and services for major health conditions and chronic diseases.[52] For example, a 2023 KFF survey found that 61 percent of uninsured adults skipped or postponed getting treatment due to cost compared to 21 percent for insured adults.[53] Similarly, a 2019 National Center for Health Statistics survey found that 36.5 percent of uninsured adults delayed or did not receive needed medical care due to cost as compared to eight percent of insured individuals.[54] That same study found that over 20 percent of individuals living at or below 200 percent of the federal poverty threshold delayed or did not receive medical care due to cost as compared to 8.5 percent of all individuals. Notably, the 2019 study showed fewer people missing care than the 2023 KFF survey, again suggesting that problems accessing care have been exacerbated by the pandemic. Given that individuals who apply for disability benefits are disproportionately uninsured [55] or low-income, a standard which helps to accommodate cost barriers to healthcare access may be appropriate.

Healthcare workforce analyses have also shown significant healthcare workforce shortages and delays in care, exacerbated by the pandemic, and have projected ongoing healthcare workforce shortages for at least a decade, further impacting access to care, with disparate access to care for different communities.[56] Preliminary data from the pandemic shows that stress during the pandemic led to burnout and retirement earlier than projected for many physicians and nurses, exacerbating workforce shortages that were already increasing due to an aging healthcare workforce.[57] At the same time, healthcare demand has increased and is expected to continue to increase due to population growth, the increase in individuals with multiple chronic conditions, and the aging population.[58] Experts in musculoskeletal care presenting to the NASEM Standing Committee reported significant persisting delays in specialty care appointments compared to pre-pandemic norms.[59] The Commonwealth Fund's 2024 report also noted that timely access to care in the United States is limited by a worsening shortage of primary care clinicians and the time spent by healthcare providers on administrative issues related to billing.[60]

The Health Resources and Services Administration (HRSA) reported in November 2023 that approximately 102 million Americans live in a primary care health professional shortage area and that maldistribution of the healthcare workforce results in severe shortages in rural communities.[61] Additionally, a 2024 HRSA report projects average physician shortages of 56 percent in non-metro areas by 2036.[62] Similarly, the Association of American Medical Colleges recently projected a shortage of up to 139,000 physicians by 2033 and concluded that if communities historically underserved by our health care system had fewer access barriers and comparable access was provided for all, the shortfall would be three to six times the magnitude of current estimates.[63]

Any ongoing decrease in the frequency of, or increase in wait times for, in-person medical visits could lead to additional barriers or delays in documenting certain findings in the medical record that are needed to meet or equal the musculoskeletal disorders listings. This is true even if the decrease in in-person visits is offset with telehealth visits that make healthcare more accessible for some, because telehealth visits cannot reliably provide all the findings provided during in-person visits. The anecdotal evidence we have suggests the possibility of ongoing changes in healthcare related to the pandemic, including significant post-PHE delays in in-person care and ongoing telehealth utilization at a higher rate than prior to the pandemic. Although this evidence may support additional flexibility in the proximity standard, there is also an overall lack of published and available data on healthcare access and utilization following the PHE on which to rely. Therefore, an extension until May 11,

[51] Gunja MZ, Gumas ED, Williams RD II, Doty MM, Shah A, Fields K. The cost of not getting care: income disparities in the affordability of health services across high-income countries. New York: Commonwealth Fund, November 16, 2023 (*https://www.commonwealthfund.org/publications/surveys/2023/nov/cost-not-getting-care-income-disparities-affordability-health*).

[52] Tolbert, J, Drake, P., & Damic, A., (2023, December 18). *Key Facts about the Uninsured Population.* The Kaiser Family Foundation. *https://www.kff.org/report-section/key-facts-about-the-uninsured-population-issue-brief/#endnote_link_607642-9.*

[53] Lopes, L., Montero, A., Presiado, M., & Hamel, L. (2024, March 01). *Americans' Challenges with Health Care Costs.* The Kaiser Family Foundation. *https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/*

[54] National Center for Health Statistics, National Health Interview Survey. See Sources and Definitions, National Health Interview Survey (NHIS) and Health, United States, 2020–2021 Table UnmtNd.

[55] For example, a 2009 study found that recent SSDI recipients were uninsured at substantially higher rates than the general population. See, Livermore, G., Stapleton, D., & Claypool, H. Health Insurance and Health Care Access Before and After SSDI Entry. New York: Commonwealth Fund, May 20, 2009. *https://www.commonwealthfund.org/publications/fund-reports/2009/may/health-insurance-and-health-care-access-and-after-ssdi-entry.*

[56] GlobalData Plc. (2024, March). *The Complexities of Physician Supply and Demand: Projections From 2021 to 2036.* AAMC; *https://www.aamc.org/media/75236/download?attachment.*

[57] Martin, B., Kaminski-Ozturk, N., O'Hara, C., & Smiley, R. (2023). Examining the Impact of the COVID–19 Pandemic on Burnout and Stress Among U.S. Nurses. *Journal of nursing regulation, 14*(1), 4–12. *https://doi.org/10.1016/S2155-8256(23)00063-7.*

[58] GlobalData Plc. (2024, March). *The Complexities of Physician Supply and Demand: Projections From 2021 to 2036.* AAMC; *https://www.aamc.org/media/75236/download?attachment.*

[59] Standaert, Christopher, M.D. COVID Disruptions and their Impact on Musculoskeletal Care. Presentation to the Standing Committee of the National Academies of Science and Medicine Health and Medicine Division, on June 20, 2024; *see also* Escorpizo, Reuben, P.T., M.Sc., D.P.T. Musculoskeletal Health, and Telehealth—Rapid Overview. Presentation to the Standing Committee of the National Academies of Science and Medicine Health and Medicine Division, on June 20, 2024.

[60] Blumenthal, D., Gumas, E., & Shah, A. (2024). The Failing U.S. Health System. *The New England journal of medicine, 391*(17), 1566–1568. *https://doi.org/10.1056/NEJMp2410855.*

[61] National Center for Health Workforce Analysis (2024, May). *State of the U.S. Health Care Workforce, 2023* HRSA; *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/state-of-the-health-workforce-report-2023.pdf.*

[62] Bureau of Health Workforce. (2024, November). *Health Workforce Projections.* HRSA; Retrieved November 22, 2024, from *https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand.*

[63] GlobalData Plc. (2024, March) *The Complexities of Physician Supply and Demand: Projections From 2021 to 2036.* AAMC; *https://www.aamc.org/media/75236/download?attachment.*

2029, is necessary to ensure a sufficient research base for a permanent standard.

We are extending the flexibility until May 11, 2029, to provide time for published research to demonstrate utilization data after the PHE. Experts in musculoskeletal care presenting to the NASEM Standing Committee in June 2024 noted that there was almost no published research about musculoskeletal health care utilization in 2022 and beyond. One expert explained that this is largely due to the logistics of scientific research, where data is collected in large databases on a delay, and researchers must obtain funding and access to the database, analyze the data, and seek peer review and publication, which typically takes several years.[64] Therefore, in order to provide time for development of the evidence base and for full notice-and-comment rulemaking, we are extending the flexibility in the proximity standard until May 11, 2029. However, we will begin the rulemaking process for a permanent proximity standard as soon as the evidence base is available.

Evidence to Review

We will continue to use the extension period to study the changes in healthcare access and provision after the expiration of the PHE. During the extension period, we will also continue to review information about disparities in access to care or modalities of care. We expect this additional period will allow us to consider whether we should revert to the 4-month ''close proximity of time'' standard, adopt a permanent change to the consecutive 12-month ''close proximity of time'' period, or use a different timeframe, to account for ongoing changes in healthcare access and delivery.

We will also continue to study the application of the ''close proximity of time'' rule in our programs. In addition, we will continue to monitor the quality of our determinations and decisions to inform our policy decision and ensure the appropriate adjudication of claims for people with musculoskeletal disorders.

Solicitation for Public Comment

Although we are publishing a temporary final rule, we invite public comment on all aspects of the rule, including:

- The appropriate standard for ''close proximity of time'' to account for barriers to access to care or changes in healthcare delivery, and the justification or evidence for the standard the commenter identifies as appropriate;
- Research, evidence, or information about barriers to access to care, changes in healthcare delivery, and disproportionate burdens faced by any subset of the population and how that impacts an individual's ability to provide the required evidence for a medical listing; and
- The expiration date of this rule.

Please share any supporting information that you might have. We will consider any substantive comments we receive within 60 days of the publication of this TFR.

Summary of the Changes

This rule revises sections 1.00C7a and 101.00C7a of the musculoskeletal disorders listings to define a new term, ''post-pandemic evaluation period,'' to mean ''the period beginning on May 12, 2025, and ending on May 11, 2029.'' We are adding this new term because we are extending the more flexible ''close proximity of time'' standard to six years after the end of the PHE. This rule also revises sections 1.00C7c and 101.00C7c to indicate that, for claims determined or decided during the pandemic period or the post-pandemic evaluation period, ''within a close proximity of time'' means that all the relevant criteria must appear in the medical record within a consecutive 12-month period.

We are making changes based on the Commissioner of Social Security's rulemaking authority specified in sections 205(a), 702(a)(5), 1631(d)(1), 1631(e)(1)(A), and 1633(a) of the Social Security Act. Under those sections, the Commissioner may adopt rules regarding, among other things, the nature and extent of evidence needed to establish benefit eligibility, as well as methods of taking and furnishing such evidence.

Justification for Foregoing Notice and Comment Rulemaking

We follow the Administrative Procedure Act's (APA) rulemaking procedures specified in 5 U.S.C. 553 when we develop regulations. Generally, the APA requires that an agency provide prior notice and opportunity for public comment before issuing a final rule. However, the APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures because they are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(B)).

We find that there is good cause to issue this TFR without prior notice and public comment.[65] We have been following the more flexible 12-month ''close proximity of time'' standard for over three years, and it would be impracticable and contrary to the public interest to disrupt our claims adjudications by delaying implementation of this TFR. Delayed implementation of this TFR would require us to either delay adjudicating affected claims, potentially resulting in delayed benefits to vulnerable individuals,[66] or apply the 4-month ''close proximity of time'' standard, which does not consider changes in healthcare access and delivery related to the PHE, as discussed in the preamble. If we applied the 4-month standard, individuals might be unable to show that they meet a listing under the 4-month ''close proximity of time'' standard merely due to changes in how the healthcare system works. Implementing this TFR, without prior notice and public comment, will allow us to maintain this more flexible standard while we review and adapt to new clinical practices and healthcare data that emerge in a post-PHE landscape.

Delay in implementing this TFR would be impracticable and contrary to the public interest because it may cause some applicants to experience immediate and severe financial hardship, placing them at risk of losing their homes, means of transportation, access to health care, and other important resources, in addition to experiencing increased stress as they await the outcome of their case and their award of benefits. This is particularly true for the population that is eligible for Supplemental Security Income (SSI), which has, by definition, severely limited income and financial resources.[67] An unnecessary delay

[64] Standaert, Christopher, M.D. COVID Disruptions and their Impact on Musculoskeletal Care. Presentation to the Standing Committee of the National Academies of Science and Medicine Health and Medicine Division, on June 20, 2024.

[65] In our first TFR, we provided notice that we would consider extending the expiration date of the rule, and we invited public comments on the expiration date. 86 FR at 38920, 38924. As discussed above, we received a public comment from NOSSCR that encouraged us to make the temporary 12-month standard permanent or, if we chose not to make the 12-month standard permanent, to extend the period covered by the first TFR to one year after the end of the PHE. Similarly, in our second TFR we provided notice that we would consider extending the expiration date of the rule, and we invited public comments on the expiration date. 88 FR at 67081, 67088. As discussed above, we received a public comment from The Connected Health Initiative which supported our decision to extend the original TFR to continue to study the impacts of the PHE and barriers to healthcare.

[66] Individuals who are eligible for disability benefits are, by definition, not able to engage in substantial gainful activity, which means they may experience immediate and severe financial hardship.

[67] 42 U.S.C. 1382(a); 20 CFR 416.202.

would cause significant harm and detract substantially from the effectiveness of the disability program in providing meaningful economic relief for disabled individuals. Even if affected claimants received the same benefits at a later date, these individuals may suffer from long term or permanent consequences of the lost income during the period of delay.

Delaying implementation of this final rule to provide an opportunity for prior notice and public comment is also unnecessary. As noted above, we have applied the more flexible 12-month ''close proximity of time'' standard for over three years, and its effects have been negligible, merely resulting in more streamlined, faster disability determinations for a very small number of claimants.

Moreover, we have given interested parties an opportunity to provide public comment on the 12-month standard—including soliciting comments about a possible extension—on two prior occasions: first when we published the 2021 TFR and then, when we extended the flexibility in September 2023. Altogether, we received two public comments. The first commenter supported making the 12-month standard permanent or, alternatively, extending it, and the second commenter supported an extension of the 12-month standard. Accordingly, delaying implementation of this rule to obtain further public comment is unnecessary.

For good cause shown, to avoid delaying benefits to vulnerable individuals while providing appropriate flexibility to account for COVID–19-related healthcare changes, we are dispensing with prior notice and public comment on this rule pursuant to 5 U.S.C. 553(b)(B).

Regulatory Procedures

Clarity of This Rule

Executive Order 12866, as supplemented by Executive Orders 13563 and 14094, requires each agency to write all rules in plain language. In addition to your substantive comments on this rule, we invite your comments on how to make the rule easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rule clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?
- Does the rule contain technical language or jargon that is not clear?
- Would a different format make the rule easier to understand, *e.g.,* grouping and order of sections, use of headings, paragraphing?

Executive Order 12866, as Supplemented by Executive Orders 13563 and 14094

We consulted with the Office of Management and Budget (OMB) and determined that this rule is a non-significant regulatory action under Executive Order 12866, as supplemented by Executive Orders 13563 and 14094.

Anticipated Transfers to Our Program

Our Office of the Chief Actuary estimates that implementation of this temporary final rule would result in negligible changes (*i.e.,* less than $500,000) in scheduled Old-Age, Survivors, and Disability Insurance benefits and Federal SSI payments.

Anticipated Administrative Cost-Savings to the Social Security Administration

The Office of Budget, Finance, and Management expects the extension provided by the TFR will have a minimal administrative effect on the agency.

Anticipated Time-Savings and Qualitative Benefits

We anticipate the following qualitative benefits generated from this policy:

- Providing a more flexible 12-month ''close proximity of time'' standard in the musculoskeletal disorders listings will potentially result in streamlined, faster disability determinations for a small number of claimants. Absent this policy, a small number of determinations might be delayed due to a need for additional medical or vocational development.

Anticipated Costs

We do not believe there are more than de minimis costs to the public associated with this rule. The requirements in this rule will not impose new additional costs outside of the normal course of business for applicants or change how the public interacts with our disability programs.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act.[68]

[68] 5 U.S.C. 801 *et seq.*

Executive Order 13132 (Federalism)

We analyzed this temporary final rule in accordance with the principles and criteria established by Executive Order 13132 and determined that the rule will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that this rule will not preempt any State law or State regulation or affect the States' abilities to discharge traditional State governmental functions.

Regulatory Flexibility Act

We certify that this temporary final rule will not have a significant economic impact on a substantial number of small entities because it affects individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

These rules do not create any new or affect any existing collections and, therefore, do not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure; Blind, Disability benefits; Old-age, survivors, and disability insurance; Reporting and recordkeeping requirements; Social Security.

20 CFR Part 416

Administrative practice and procedure; Aged, Blind, Disability cash payments; Public assistance programs; Reporting and recordkeeping requirements; Supplemental Security Income (SSI).

The Acting Commissioner of Social Security, Carolyn W. Colvin, having reviewed and approved this document, is delegating the authority to electronically sign this document to Erik Hansen, who is a Federal Register Liaison for the Social Security Administration, for purposes of publication in the **Federal Register**.

Erik Hansen,

Associate Commissioner, Office of Legislative Development and Operations, Social Security Administration.

For the reasons stated in the preamble, we are amending subpart P of

part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—Determining Disability and Blindness

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: 42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. In appendix 1 to subpart P of part 404:

■ a. In part A, amend section 1.00C7 by revising paragraphs a and c; and

■ b. In part B, amend section 101.00C7 by revising paragraphs a and c.

The revisions read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

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Part A

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1.00 Musculoskeletal Disorders

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C. * * *

7. * * *

a. The term *pandemic period* as used in 1.00C7c means the period beginning on April 2, 2021, and ending on May 11, 2025. The term *post-pandemic evaluation period* as used in 1.00C7c means the period beginning on May 12, 2025, and ending on May 11, 2029.

* * * * *

c. For 1.15, 1.16, 1.17, 1.18, 1.20C, 1.20D, 1.22, and 1.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. The phrase ''within a close proximity of time'' means that all of the relevant criteria must appear in the medical record within a consecutive 4-month period, except for claims determined or decided during the pandemic period or post-pandemic evaluation period. For claims determined or decided during the pandemic period or post-pandemic evaluation period, all of the relevant criteria must appear in the medical record within a consecutive 12-month period. When the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset. For listings that use the word ''and'' to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.

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Part B

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101.00 Musculoskeletal Disorders.

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C. * * *

7. * * *

a. The term *pandemic period* as used in 101.00C7c means the period beginning on April 2, 2021, and ending on May 11, 2025. The term *post-pandemic evaluation period* as used in 101.00C7c means the period beginning on May 12, 2025, and ending on May 11, 2029.

* * * * *

c. For 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. The phrase ''within a close proximity of time'' means that all of the relevant criteria must appear in the medical record within a consecutive 4-month period, except for claims determined or decided during the pandemic period or post-pandemic evaluation period. For claims determined or decided during the pandemic period or post-pandemic evaluation period, all of the relevant criteria must appear in the medical record within a consecutive 12-month period. When the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset. For listings that use the word ''and'' to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.

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[FR Doc. 2025–01283 Filed 1–16–25; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 16

[Docket No. FDA–2024–N–3654]

RIN 0910–AI97

Regulatory Hearing Before the Food and Drug Administration; General Provisions; Amendments; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) published in the **Federal Register** of September 20, 2024, a direct final rule amending the Scope section of our regulation that provides for a regulatory hearing before the Agency. The comment period closed December 4, 2024. FDA is withdrawing the direct final rule because the Agency received significant adverse comment.

DATES: The direct final rule published at September 20, 2024, 89 FR 77019, is withdrawn effective January 17, 2025.

FOR FURTHER INFORMATION CONTACT: Robert Schwartz, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on September 20, 2024, 89 FR 77019 is withdrawn.

Dated: January 13, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01145 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2022–C–0098]

Listing of Color Additives Exempt From Certification; Myoglobin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of myoglobin as a color additive in ground meat and ground poultry analogue products. We are taking this action in response to a color additive petition (CAP) submitted by Motif FoodWorks, Inc. (Motif FoodWorks or petitioner).

DATES: This order is effective February 19, 2025. See section X for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the order must be submitted by February 18, 2025.

ADDRESSES: You may submit objections and requests for a hearing as follows.