b. *Project No.:* 10441–020.
c. *Date Filed:* April 8, 2025.
d. *Applicant:* City of Aspen, Colorado.
e. *Name of Project:* Maroon Creek Hydroelectric Project.
f. *Location:* On Maroon Creek in Pitkin County, Colorado.
g. *Filed Pursuant to:* 18 CFR 16.22 and the Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2705, 2708, *amended by* the Hydropower Regulatory Efficiency Act of 2013, Public Law 113–23, 127 Stat. 493 (2013).
h. *Applicant Contact:* Phil Overenyder at City of Aspen at (970) 920–5111; or email at *phil.overeynder@aspen.gov*.
i. *FERC Contact:* Lee Baker at (202) 502–8554, or *everard.baker@ferc.gov*.
j. *Cooperating Agencies:* Federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).
k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.
l. *Deadline for filing additional study requests and requests for cooperating agency status:* July 7, 2025.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx*. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Maroon Creek Hydroelectric Project (P–10441–020).

m. The application is not ready for environmental analysis at this time.

n. *The existing project works consist of:* (a) a 10-foot-high, 40-foot-long reinforced concrete dam with a crest elevation of 8,245.75 feet (the Maroon Creek diversion dam); (b) a small impoundment; (c) an intake structure at the dam; (d) a 39-inch-diameter, 5,563-foot-long buried reinforced concrete penstock; (e) a 27-inch-diameter, 1,317-foot-long buried reinforced concrete penstock together with a 110-foot section of steel penstock leading to the powerhouse; (f) a powerhouse with a 450-kW turbine-generator unit; (g) a 200-foot-long trapezoidal open channel tailrace, returning the water to Maroon Creek; (h) a 0.48-kV generator leading to a three-phase, 0.48/24.9-kV step-up transformer; (i) an approximately 400-foot-long, 24.9-kV overhead power line tap connection to the Aspen Highlands circuit operated by Holy Cross Energy; and (j) appurtenant facilities.

The application describes the addition of up to 50 kW of generating capacity through two new small turbines, with two new attached generators placed at the existing diversion dam. These new units would generate power from the bypass flows released from the diversion dam without changing the time or the amount of those releases. Flows utilized by new generation equipment would be returned to the same location on the stream immediately below the dam and headgate.

o. A copy of the application can be viewed on the Commission's website at *http://www.ferc.gov,* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document (P–10441). For assistance, contact FERC at *FERCOnlineSupport@ferc.gov,* or call toll-free, (866) 208–3676 or (202) 502–8659 (TTY).

p. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organizations, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

q. *Procedural schedule and final amendments:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Issue Deficiency Letter and Additional Information Request (if necessary).	June 2025.
Issue Acceptance Letter	September 2025.
Issue Scoping Document 1 for comments.	October 2025.
Issue Scoping Document 2 (if necessary).	January 2026.
Issue Notice of Ready for Environmental Analysis.	January 2026.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: May 6, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–08293 Filed 5–9–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–209, CMS–R–52, CMS–10538, CMS–10171, and CMS–10780]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments

regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by June 11, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Laboratory Personnel Report (CLIA) and Supporting Regulations; *Use:* The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. The surveyor will provide the laboratory with the CMS–209 form. While the surveyor performs other aspects of the survey, the laboratory will complete the CMS–209 by recording the personnel data needed to support their compliance with the personnel requirements of CLIA. For this submission, we are making minor revisions to the collection instrument. We revised the instructions for clarity and removed the references to specific regulations. *Form Number:* CMS–209 (OMB control number 0938–0151); *Frequency:* Biennially; *Affected Public:* Private Sector—State, Local, or Tribal Governments; and Federal Government; *Number of Respondents:* 16,404; *Total Annual Responses:* 8,202; *Total Annual Hours:* 4,101. (For policy questions regarding this collection contact Penny Keller at 410–786–2035.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease (ESRD) Conditions for Coverage and Supporting Regulations; *Use:* The Centers for Medicare and Medicaid Services (CMS) is requesting reinstatement of OMB Control number 0938–0386 (CMS–R–52) in compliance with the Paperwork Reduction Act (PRA). This package applies to existing Medicare End-stage Renal Disease (ESRD) conditions for coverage (CfCs) at 42 CFR 494. Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603) originally extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292) amended title XVIII of the Social Security Act (the Act) by adding section 1881. Section 1881(b)(1) of the Act authorizes the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services to patients must meet to qualify for Medicare reimbursement. Final regulations were published June 3, 1976. Subsequent to the publication of the final regulations, the ESRD Amendments of 1978 were enacted to amend title XVIII of the Act to include section 1881(c). This section establishes ESRD network areas and Network organizations to assure the effective and efficient administration of ESRD program benefits. The requirements from section 1881(b) and (c) are implemented in regulations at 42 CFR part 405, subpart U, Conditions for Coverage for dialysis facilities.

On April 7, 1986, the Consolidated Omnibus Budget Reconciliation Act of 1975 (COBRA) (P.L. 99–272) was enacted which requires the Secretary to maintain renal disease Network organizations as authorized under section 1881(c) of the Act, and not merge the Network organizations into other organizations or entities. On April 15, 1986, we published a notice of proposed rulemaking to implement section 9214 of Public Law 99–272. A final rule (HSQ–115) was published August 26, 1986, which included information collection requirements at § 405.2112(e). This rule revised the requirements in regulations pertaining to the ESRD networks and organizations and establishes new, more efficient Network organizations.

Revisions resulting from two additional rules: HSQ–137—ESRD: Responsibilities of Network Organizations, published January 21, 1988; and BERC–434—Medicare Program: Standards for the Reuse of Hemodialyzer Filters and Other Dialysis Supplies, published October 2, 1987, are also included. HSQ–137–ESRD approved information collection requirements at §§ 405.2112(f) and (j). BERC–434 approved information collection requirements stemming from the following historical sections of the CFR including §§ 405.2136(b), 405.2138(a), 405.2139(a), and 405.2140(b) and (c).

Major revisions to the CFR established new ESRD CfCs at 42 CFR 494 issued in a final rule, ''*Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities,*'' published on April 15, 2008 (CMS–3818–F). This rule modified, removed, added, and redesigned CfCs that dialysis facilities must meet to be certified under the Medicare program. This rule approved information collection requirements at §§ 494.30, 494.40, 494.50, 494.60, 494.70, 494.80, 494.90, 494.100, 494.110, 494.120, 494.150, 494.170, and 494.180.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by CMS–3818–F at 414.330(a)(2)(iii)(C). The burden to ESRD home dialysis suppliers associated with this requirement would be the time and effort necessary to collect all data for each patient receiving home dialysis care with respect to services and items furnished. However, the payment method that covered these suppliers

was eliminated in 2011 and there are no longer any such entities. See 42 CFR parts 410, 413 and 414 Medicare Program; End-Stage Renal Disease Prospective Payment System; Final Rule and Proposed Rule at the following link **Federal Register** *https://www.govinfo.gov/content/pkg/FR-2010-08-12/pdf/2010-18466.pdf.* Therefore, there are no actual costs associated with this requirement; we removed it from this package.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by interim final rule, ''*Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment,*'' published on December 14, 2016 (CMS–3337–IFC). This rule established new requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans. This interim final rule established additional burden associated with §§ 494.70(c) and 494.180(k); these were quantified in the preceding information collection which expired in 2024 (OMB control number 0938–0386). Since these regulations were not finalized due to litigation, they are no longer in effect. Therefore, we took out these sections from this package as they do not impose any burden.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by final rule, ''*Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers,*'' published September 16, 2016 (CMS–3178–F). This rule established the creation and maintenance of an Emergency Preparedness Plan at 494.62(a), an Emergency Preparedness Policies and Procedures document at 494.62(b), an Emergency Preparedness Communication Plan at 494.62(c), a training program 494.62(d), and documentation of training exercises 494.62(e). These information collections are in separate package, OMB Control number 0938–1325.

On July 5, 2024, revisions to the CfC were proposed in ''*Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,*'' (CMS–1805–P). This rule proposed to expand coverage of home dialysis services to patients with acute kidney injury (AKI). Since the ESRD CfCs apply to dialysis facilities, not to people with ESRD, this rule proposes to revise language in the CfCs to allow beneficiaries with AKI to utilize home dialysis. Specifically, we refer to facilities abiding by the ESRD CfCs as 'dialysis facilities' opposed to 'ESRD facilities and all patients seeking services from dialysis facilities as 'patients' rather than 'ESRD patients.' There is no ICR burden associated with these changes however we made confirming changes to the language in this package.

The CfCs are used by Federal (CMS), State surveyors (employed by State survey agencies), or CMS authorized accrediting organizations as a basis for determining whether a dialysis facility qualifies for approval or re-approval under Medicare. Surveyors make an in-person visit to the dialysis facility to perform the complete survey.

The preceding information collection, which expired on March 31, 2024, estimated the total annual hourly burden as 1,260,491 hours at a cost of $64,839,657. We revise this to 800,621 hours at a cost of $49,638,502. The reduction in hours and cost is largely due to removing the burden estimates that no longer apply. *Form Number:* CMS–R–52 (OMB control number: 0938–0386); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 8,048; *Total Annual Responses:* 215,591; *Total Annual Hours:* 800,621 (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

3. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Hospice Information for Medicare Part D Plans; *Use:* The Social Security Act in section 1861(dd) and Federal regulations in 42 CFR 418.106 and § 418.202(f) require hospice programs to provide individuals under hospice care with drugs and biologicals related to the palliation and management of the terminal illness as defined in the hospice plan of care. Medicare payment is made to the hospice for each day an eligible beneficiary is under the hospice's care, regardless of the amount of services provided on any given day. Because hospice care is a Medicare Part A benefit, drugs provided by the hospice and covered under the Medicare payment to the hospice program are not covered under Part D.

The form would be completed by the prescriber or the beneficiary's hospice, or if the prescriber or hospice provides the information verbally to the Part D sponsor, the form would be completed by the sponsor. Information provided on the form would be used by the Part D sponsor to establish coverage of the drug under Medicare Part D. Per statute, drugs that are necessary for the palliation and management of the terminal illness and related conditions are not eligible for payment under Part D. The standard form provides a vehicle for the hospice provider, prescriber or sponsor to document that the drug prescribed is ''unrelated'' to the terminal illness and related conditions. It also gives a hospice organization the option to communicate a beneficiary's change in hospice status and/care plan to Part D sponsors. *Form Number:* CMS–10538 (OMB control number: 0938–1296); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profits); *Number of Respondents:* 319; *Number of Responses:* 57,027; *Total Annual Hours:* 2,329. (For policy questions regarding this collection, contact Chad Buskirk at (410) 786–1630 or *chad.buskirk@cms.hhs.gov*.)

4. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Part D Coordination of Benefits Data; *Use:* Sections 1860D–23 and 1860D–24 of the Act require the Secretary to establish requirements for prescription drug plans to promote effective coordination between Part D plans and SPAPs and other payers. These Part D Coordination of Benefits (COB) requirements have been codified into the Code of Federal Regulations at 42 CFR 423.464. In particular, CMS' requirements relate to the following elements: (1) enrollment file sharing; (2) claims processing and payment; (3) claims reconciliation reports; (4) application of the protections against high out-of-pocket expenditures by tracking TrOOP expenditures; and (5) other processes that the Secretary determines.

This information collection request assists CMS, pharmacists, Part D plans, and other payers coordinate prescription drug benefits at the point-of-sale and track beneficiary True out-of-pocket (TrOOP) expenditures using the Part D Transaction Facilitator (PDTF). *Form Number:* CMS–10171 (OMB control number: 0938–0978); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 67,043; *Total Annual Responses:* 935,730,342; *Total Annual Hours:* 1,011,740. (For policy questions regarding this collection contact Chad Buskirk at 410–786–1630 or *chad.buskirk@cms.hhs.gov*.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Requirements

Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in; *Use:* On December 27, 2020, the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which included the No Surprises Act, was signed into law. The No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise medical bills arise most frequently. The July 13, 2021 interim final rules ''Requirements Related to Surprise Billing; Part I'' (86 FR 36872, July 2021 interim final rules) issued by the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, and the Office of Personnel Management, implement provisions of the No Surprises Act that apply to group health plans, health insurance issuers offering group or individual health insurance coverage, and carriers in the Federal Employees Health Benefits (FEHB) Program that provide protections against balance billing and out-of-network cost sharing with respect to emergency services, non-emergency services furnished by nonparticipating providers related to patient visits to certain types of participating health care facilities, and services furnished by nonparticipating providers of air ambulance services. The July 2021 interim final rules prohibit nonparticipating providers, emergency facilities, and providers of air ambulance services from balance billing participants, beneficiaries, and enrollees in certain situations unless they satisfy certain notice and consent requirements. The No Surprises Act and the July 2021 interim final rules require group health plans and issuers of health insurance coverage to provide information about qualifying payment amounts (QPAs) to nonparticipating providers and facilities and to provide disclosures on patient protections against balance billing to participants, beneficiaries and enrollees. Self-insured plans opting in to a specified State law are required to provide a disclosure to participants. Certain nonparticipating providers and nonparticipating emergency facilities may provide participants, beneficiaries, and enrollees with notice and obtain their consent to waive balance billing protections, provided certain requirements are met. In addition, certain providers and facilities are required to provide disclosures on patient protections against balance billing to participants, beneficiaries and enrollees. The No Surprises Act requires the Secretary of HHS to audit no more than 25 group health plans and health insurance issuers offering group or individual health insurance coverage annually, and permits additional audits based on complaints, to ensure that such plans and coverage are in compliance with the requirement of applying a QPA and that the QPA applied satisfies the definition under the No Surprises Act with respect to the year involved. *Form Number:* CMS–10780 (OMB control number: 0938–1401); *Frequency:* On Occasion; *Affected Public:* Individuals, State, Local, or Tribal Governments, Private Sector; *Number of Respondents:* 2,477,197; *Total Annual Responses:* 85,148,199; *Total Annual Hours:* 6,006,654. (For policy questions regarding this collection, contact Russell Tipps at 667–290–9640.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–08307 Filed 5–9–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–E–3272; FDA–2023–E–3273; FDA–2023–E–3274; FDA–2023–E–3276; FDA–2023–E–3296; and FDA–2023–E–3297]

Determination of Regulatory Review Period for Purposes of Patent Extension; SKYCLARYS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SKYCLARYS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by July 11, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 10, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 11, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2023–E–3272; FDA–2023–E–3273;