The public relations firm that HISA is working with has many years of expertise in P/R for thoroughbred racing enterprises. The firm can perform the aforementioned tasks more efficiently and effectively than if HISA were to hire staff to perform these tasks in-house.

o. *Legal—General and Lawsuits.* This includes the cost of outside legal counsel for the creation, management, and updating of Racetrack Safety and ADMC rules as well as the cost of outside counsel that is working on the various lawsuits in which HISA is a party. Additionally, this includes the cost of outside legal counsel that handles enforcement actions brought under the Racetrack Safety Program. Doing all these tasks requires a decentralized group of lawyers with varied skill sets. At present, it is much more efficient and effective to utilize outside counsel than for HISA to hire a large in-house legal team to handle these issues.

p. *Insurance.* This includes the following insurance policies for HISA:

i. Directors & Officers Policy with Employment Practices Liability Coverage.

ii. Cyber insurance.

iii. General Liability insurance with Terrorism Coverage.

All of these policies were competitively shopped by a broker to get the lowest rate possible.

q. *Payroll Services.* This includes all costs of HISA's relationship with Resource Management, Inc. (RMI), a Professional Employer Organization (PEO). RMI provides Human Resources administration (handbook and policy management resources, new employee onboarding, labor law assistance, etc.), benefits management, compliance services (workers' compensation claims management and annual reporting, unemployment claims management, etc.), and payroll administration (payroll processing, W2 management, vacation tracking, etc.). The relationship with RMI allows these functions to be performed in a more cost-effective manner than if HISA hired employees to perform those functions.

r. *Printing and Publication.* This includes the cost of printing and publishing various educational and communication materials.

s. *Professional Services.* This account consists of:

i. Consulting fees to independent contractors assisting HISA with consulting projects and board and executive functions.

ii. $75,000 contingency fund set aside for unexpected expenses.

These items will ensure that HISA has high-quality employees who are well-trained to properly serve its constituents.

Please note that the 2026 HISA budget contemplates the repayment of $0 of loans; it does not assume that any funding shortfall will be incurred. VI. *Information Concerning Rule 1.150(c)(5).* Attached as Appendix 10 is a comparison of the approved HISA 2025 Budget through June 30, 2025 to actual revenues and expenditures during that same period. A variance has been calculated for each line item, and a narrative explanation has been provided for all variances >10% and at least $100,000.

VII. *Information Concerning Rule 1.150(c)(6).* The Authority received no public comments after posting the proposed budget on its website. Therefore, the Authority did not make any changes to the proposed budget in response to comments received.

**HISA's Conclusion**

The proposed budget is consistent with and serves the goals of the Act in a prudent and cost-effective manner. The proposed budget allocates the funding necessary for the successful implementation by HISA of the requirements of the Act. The budget has been carefully analyzed and is narrowly tailored to the various regulatory activities of HISA as contemplated by the Act. As demonstrated herein, the anticipated revenues are sufficient to meet its anticipated expenditures.

**End Notes**

[1] Codified at 15 U.S.C. 3051 through 3060.

[2] Public Law 116–260, 134 Stat. 1182, 3252 (Dec. 27, 2020).

[3] Public Law 117–328, 136 Stat. 4459, 5231 (Dec. 29, 2022).

[4] 88 FR 18034 (Mar. 27, 2023). These rules were amended in February 2024. 89 FR 8530 (Feb. 8, 2024); *see* 16 CFR 1.150—1.152.

[5] 15 U.S.C. 3051 through 3060.

[6] 16 CFR part 1 Subpart U.

[7] The Authority notes that it has adopted and implemented a Conflicts of Interest and Business Ethics Policy (the ''Policy'') which acknowledges that Authority ''[r]epresentatives involved in procurement have a special responsibility to adhere to principles of fair competition in the purchase of products and services by selecting vendors based exclusively on standard commercial considerations, such as quality, cost, availability, service and reputation, and not on the receipt of special favors.'' The Policy requires, among other things, transactions to be supported by appropriate documentation; no entry be made in our books and records that intentionally hides or disguises the nature of any transaction or of any of our liabilities, or misclassifies any transactions as to accounts or accounting periods; HISA Representatives comply with our system of internal controls; no cash or other assets be maintained for any purpose in any unrecorded or ''off-the-books'' fund; no HISA Representative may take or authorize any action that would cause our financial records or financial disclosures to fail to comply with generally accepted accounting principles or other applicable laws, rules, and regulations; and all HISA Representatives must cooperate fully with our finance staff, as well as our independent public accountants and legal counsel, and respond to their questions with candor and provide them with complete and accurate information to help ensure that our records are accurate and complete. Any HISA Representative who becomes aware of any departure from these standards has a responsibility to report his or her knowledge promptly to the CEO or Chair of the Board. A copy of the Policy is available to the public on the Authority's website.

[8] A modification of the Racetrack Safety Rule was approved by the Commission by Order dated June 7, 2024.

[9] In 2023, the HISA Accreditation Team completed accreditation visits at 21 racetracks. In 2024, they completed 22 accreditation site visits. Thus far in 2025, the HISA Accreditation Team has completed accreditation visits at 16 racetracks.

By direction of the Commission.

**Joel Christie,**

*Acting Secretary.*

[FR Doc. 2025–16858 Filed 9–2–25; 8:45 am]

**BILLING CODE 6750–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–10666]**

### Agency Information Collection Activities: Proposed Collection; 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by November 3, 2025.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 N. Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10666 Non-Exchange Entities

Under the 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 requires federal agencies to publish a 60-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.

**Information Collections**

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Non-Exchange Entities*; Use:* The original information collection request (ICR) that provided the authority for HHS to collect the information necessary for these requests to deviate was titled Non-Exchange Entities (0938–1329) and was approved on 5/23/2017. The original ICR was discontinued on 3/4/2020 due to the concurrent discontinuation of standardized options in the HHS Notice of Benefit and Payment Parameters for 2019; Final Rule (2019 Payment Notice).

The ICR that provided HHS the authority to collect the necessary information to enable web-brokers and issuers using the Classic DE and EDE pathways to submit a request to deviate from the manner in which standardized plan options are differentially displayed on *HealthCare.gov* was reinstated concurrently with the reintroduction of standardized plan option requirements in the HHS Notice of Benefit and Payment Parameters for 2023 Final Rule (2023 Payment Notice). The standardized plan options that were differentially displayed on *HealthCare.gov* and that web-brokers or issuers utilizing the Classic DE and EDE pathways were required to differentially display were updated in the HHS Notice of Benefit and Payment Parameters for 2024 Final Rule (2024 Payment Notice) and HHS Notice of Benefit and Payment Parameters for 2025 Final Rule (2025 Payment Notice). This ICR serves as a formal request to reinstate the data collection with change. *Form Number:* CMS–10666 (OMB control number: 0938–1329)*; Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 115*; Number of Responses:* 115*; Total Annual Hours:* 215. (For questions regarding this collection, contact Nikolas Berkobien at (667) 290–9903).

**William N. Parham, III,**

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

[FR Doc. 2025–16803 Filed 9–2–25; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2025–N–0008]**

### General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA. In addition, the Committee will meet to discuss and provide advice to FDA on devices used in pandemic preparedness and response to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA). The meeting will be open to the public. FDA is establishing a docket for public comment.

**DATES:** The meeting will be held virtually on October 8, 2025, from 9 a.m. to 3:30 p.m. Eastern Time.

**ADDRESSES:** This meeting will be held, and all meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2025–N–0008. The docket will close on November 10, 2025. 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