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**Question 1:**

Please confirm that “FDA-approved devices” is intended to mean “FDA-listed devices” (i.e., a device that is FDA-listed under the applicable lowest risk Class I, 510(k)-exempt classification). If a different meaning is intended, we would appreciate clarification.

Response:

Applicants should refer to Section 3 – Minimum Qualifications and Section 4.B – Product Information. The RFP requires applicants to provide FDA market authorization details for the proposed device and to demonstrate compliance with applicable federal regulatory standards. Marion County Public Health Department will evaluate submissions based on the information provided in response to the requirements outlined in the RFP.

**Question 2:**

Section 4.B requests FDA market-authorization details “e.g., 510(k) number.” Because dermatoscopes are 510(k)-exempt, will MCPHD accept evidence of an FDA device listing as fully satisfying the market-authorization requirement, in place of a 510(k) number?

Response:

Applicants should refer to Section 4.B – Product Information, which requests FDA market authorization details, including examples such as a 510(k) number and intended use. Applicants should submit the regulatory documentation applicable to their proposed device and clearly describe its regulatory status. Evaluation will be based upon the information submitted in accordance with the RFP requirements.

**Question 3:**

Section 4.B requests “evidence of ISO 13485 certification.” Please confirm that providing the ISO 13485:2016 certification of our contracted/subcontracted dermatoscope device manufacturer fully satisfies this requirement and is the appropriate basis for evaluating manufacturing-quality compliance under the now-effective QMSR framework.

Response:

Applicants should refer to Section 4.B – Product Information. The RFP requests evidence of ISO 13485 certification. Applicants should provide documentation demonstrating compliance with this requirement and include any supporting information they believe is relevant to the evaluation of manufacturing quality systems.

**Question 4:**

We fully share MCPHD’s goal of complete traceability across all 1,475 units and can



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deliver the same audit utility through serial-number tracking integrated into site-level delivery manifests, with voluntary UDI labeling as well. This approach lets MCPHD track and audit every device down to the specific clinic site. And under our 5-years warranty program, any device that needs repair is automatically replaced with a new one at no cost, which minimizes the burden of device tracking and frees up MCPHD and everyone's valuable time for pressing matters. Will MCPHD accept individual serial-number tracking and voluntary UDI labeling, fully integrated into site-level delivery manifests, as satisfying the device-tracking requirement, in place of a GUDID record, which is statutorily exempt for this lowest risk device class?

Response:

Applicants should refer to Section 4.C – Delivery and Implementation Plan, specifically the requirement for recall/discontinuation contingency plans, serial number tracking, and site-level delivery manifests. MCPHD will evaluate proposed tracking and accountability methods based upon their ability to support implementation, inventory management, and traceability objectives outlined in the RFP.

**Question 5:**

Section 4.B requests replacement part numbers. Because manufacturers routinely revise part numbers across production runs, a number captured today may not match what is supplied at delivery. Would MCPHD instead accept a service-level commitment, e.g., overnight replacement of any device at no cost across a 5-year coverage period, guaranteed spare-device availability, and spare parts-availability commitment, as a stronger basis for evaluating warranty and customer support excellence instead of a static part number?

Response:

Applicants should refer to Section 4.B – Product Information. The RFP requests warranty information, including replacement part numbers, warranty coverage periods, expected service life, and technical support information. Applicants may provide additional information regarding warranty support, replacement services, and customer support capabilities as part of their proposal.

**Question 6:**

The RFP requests battery runtime and recharge time. In rural primary care, dermatoscopes are used intermittently and typically remain docked between uses. Could MCPHD clarify how runtime and recharge time factor into scoring for an intermittent-use workflow, so we can present the most relevant information?

Response:

Applicants should refer to Section 4.B – Product Information and Section 5 – Evaluation



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Criteria. Battery runtime and recharge time are requested as part of the technical specifications that contribute to the overall evaluation of device quality and functionality. Applicants should provide complete information responsive to the requirements outlined in the RFP.

**Question 7:**

More broadly, would MCPHD consider weighting the warranty response toward coverage period, service responsiveness, and guaranteed speed of full-device replacement, rather than itemized component-level specifications? We believe this better reflects the support experience providers will actually receive.

Response:

Applicants should refer to Section 5 – Evaluation Criteria. Evaluation criteria and associated weights are established within the RFP. Applicants are encouraged to provide comprehensive information regarding warranty coverage, service responsiveness, replacement processes, and ongoing support as part of their proposal.

**Question 8:**

Have the 1,475 recipient providers or sites already been identified, or is the awardee expected to assist with identifying and recruiting them?

Response:

Applicants should refer to Section 1 – Purpose and Section 4.C – Delivery and Implementation Plan. The RFP requires applicants to provide dermatoscopes for distribution and MCPHD will determine all other implementation activities including identification of providers or sites.

**Question 9:**

What is the basis for the 1,475 figure (e.g., one per provider, per exam room, or per clinic)? This helps us size both the device order and the training appropriately.

Response:

Applicants should refer to Section 1 – Purpose, which identifies the procurement quantity as 1,475 dermatoscopes for distribution. Applicants should develop their proposals based on the quantities specified within the RFP.

**Question 10:**

Will delivery be to a single MCPHD location for redistribution, or direct to each participating site?



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Response:

Applicants should refer to Section 2.A – Dermatoscope Procurement and Delivery and Section 4.C – Delivery and Implementation Plan. Applicants are requested to provide a proposed distribution and logistics plan for consideration as part of their submission that can include one single location to MCPHD or multiple delivery locations determined collaboratively between Marion County Public Health Department and the awarded contractor

**Question 11:**

Are recipients individual primary care providers, clinic sites, or larger health systems?

Response:

Applicants should refer to Section 1 – Purpose, which identifies implementation within participating healthcare settings for individual Primary Care Providers.

**Question 12:**

Does MCPHD have a preference for how the first group of recipients is prioritized, or is that for the awardee to recommend?

Response:

Applicants should refer to Section 4.C – Delivery and Implementation Plan. Applicants will not be asked to prioritize recipients but to provide their implementation approach in providing the required quantity.

**Question 13:**

Is the August 1 – October 30, 2026 delivery window firm, or is the priority simply completion within calendar year 2026? (Phased delivery is noted as acceptable; we want to plan logistics accordingly.)

Response:

Applicants should refer to Section 2.B – Delivery Timeline and Section 4.C – Delivery and Implementation Plan. The RFP identifies a delivery period of August 1, 2026 through October 30, 2026 and permits phased deliveries during this time period. Applicants should submit proposed timelines consistent with the requirements outlined in the RFP.

**Question 14:**

Approximately how many providers require training, and what geographic spread should we anticipate? This informs the mix of in-person, virtual, and recorded delivery.



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Response:

Applicants should refer to Section 2.C – Education and Training Services and Section 4.D – Educational and Training Plan. Applicants should propose training approaches capable of supporting implementation within participating healthcare settings and describe available training formats and delivery methods including live and record virtual training and print materials. All providers receiving devices will require training.

**Question 15:**

Will MCPHD facilitate access to and scheduling with providers for training, or is training recruitment the awardee’s responsibility?

Response:

Applicants should refer to Section 2.C – Education and Training Services and Section 4.D – Educational and Training Plan. Applicants should describe their proposed training and implementation approach, including any assumptions related to scheduling, coordination, and provider participation.

**Question 16:**

Has MCPHD identified preferred specialist dermatology providers for the referral pathway, or is establishing that referral network part of the awardee’s scope?

Response:

Applicants should refer to Section 2.C – Education and Training Services. The RFP requests educational content related to referral considerations and early detection practices. Applicants should describe how these topics will be incorporated into their training materials and educational resources. Referral network pathways are not part of the RFP.

**Question 17:**

The Iowa Department of Health and Human Services’ Combat Cancer Prevention Screening RFP (Dec 2025) referenced budget guidance of \$1,920 per dermatoscope. Has that figure changed, and is there a total project budget or a per-unit ceiling we should design toward?

Response:

Applicants should refer to Section 4.E – Cost Proposal. The RFP requests applicants submit detailed pricing information, including unit costs, total project costs, training costs, and any optional services. No additional budget guidance beyond the information contained within the RFP is being provided.



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**Question 18:**

Are interviews and product demonstrations anticipated as part of scoring, or will evaluation be based on the written response only?

Response:

Applicants should refer to Section 5 – Evaluation Criteria. Marion County Public Health Department reserves the right to request additional information, negotiate terms, or reject any or all proposals. Applicants should submit complete written proposals responsive to all RFP requirements. No interviews or demonstrations are anticipated.

**Question 19:**

May an applicant propose a single dermatoscope device model, or may we offer providers a small menu of vetted options? Some providers have prior dermatoscope experience and brand preferences, and offering choice may improve adoption.

Response:

Applicants should refer to Section 4.B – Product Information. Applicants should clearly describe the proposed dermatoscope(s), associated specifications, regulatory information, and implementation approach. Proposals will be evaluated based upon responsiveness to the requirements and evaluation criteria established within the RFP.