

performance, by conducting analytical studies. For each analytical study, relevant details must be documented (e.g., the origin of the study slides and images, reader/annotator qualifications, method of annotation, location of the study site(s), challenging diagnoses, etc.). The analytical studies must include:

(A) Bench testing or technical testing to assess device output, such as localization of ROIs within a pre-specified threshold. Samples must be representative of the entire spectrum of challenging cases likely to be encountered when the device is used as intended; and

(B) Data from a precision study that demonstrates device performance when used with multiple input devices (e.g., WSI scanners) to assess total variability across operators, within-scanner, between-scanner and between-site, using clinical specimens with defined, clinically relevant, and challenging characteristics likely to be encountered when the device is used as intended. Samples must be representative of the entire spectrum of challenging cases likely to be encountered when the device is used as intended. Precision, including performance of the device and reproducibility, must be assessed by agreement between replicates.

(iii) Data demonstrating acceptable, as determined by FDA, clinical validation must be demonstrated by conducting studies with clinical specimens. For each clinical study, relevant details must be documented (e.g., the origin of the study slides and images, reader/annotator qualifications, method of annotation, location of the study site(s) (on-site/remote), challenging diagnoses, etc.). The studies must include:

(A) A study demonstrating the performance by the intended users with and without the software device (e.g., unassisted and device-assisted reading of scanned WSI of pathology slides). The study dataset must contain sufficient numbers of cases from relevant cohorts that are representative of the scope of patients likely to be

encountered given the intended use of the device (e.g., subsets defined by clinically relevant confounders, challenging diagnoses, subsets with potential biopsy appearance modifiers, concomitant diseases, and subsets defined by image scanning characteristics, etc.) such that the performance estimates and confidence intervals for these individual subsets can be characterized. The performance assessment must be based on appropriate diagnostic accuracy measures (e.g., sensitivity, specificity, predictive value, diagnostic likelihood ratio, etc.).

(B) [Reserved]

Dated: January 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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LEGAL SERVICES CORPORATION

45 CFR Part 1611

Income Level for Individuals Eligible for Assistance

AGENCY: Legal Services Corporation.

ACTION: Final rule.

SUMMARY: The Legal Services Corporation (LSC) is required by law to establish maximum income levels for individuals eligible for legal assistance. This document updates the specified income levels to reflect the annual amendments to the Federal Poverty Guidelines issued by the U.S. Department of Health and Human Services (HHS).

DATES: Effective February 2, 2023.

FOR FURTHER INFORMATION CONTACT: Karly Satkowiak, Staff Attorney, Legal Services Corporation, 3333 K St. NW, Washington, DC 20007; (202) 295-1633 satkowiakk@lsc.gov.

SUPPLEMENTARY INFORMATION: Section 1007(a)(2) of the Legal Services Corporation Act (Act), 42 U.S.C.

2996f(a)(2), requires LSC to establish maximum income levels for individuals eligible for legal assistance. Section 1611.3(c) of LSC's regulations establishes a maximum income level equivalent to 125% of the Federal Poverty Guidelines (Guidelines), which HHS is responsible for updating and issuing. 45 CFR 1611.3(c).

Each year, LSC updates appendix A to 45 CFR part 1611 to provide client income eligibility standards based on the most recent Guidelines. The figures for 2023, set out below, are equivalent to 125% of the Guidelines published by HHS on January 19, 2023.

In addition, LSC is publishing a chart listing income levels that are 200% of the Guidelines. This chart is for reference purposes only as an aid to recipients in assessing the financial eligibility of an applicant whose income is greater than 125% of the applicable Guidelines amount, but less than 200% of the applicable Guidelines amount (and who may be found to be financially eligible under duly adopted exceptions to the annual income ceiling in accordance with 45 CFR 1611.3, 1611.4, and 1611.5).

Except where there are minor variances due to rounding, the amount by which the guideline increases for each additional member of the household is a consistent amount.

List of Subjects in 45 CFR Part 1611

Grant programs—law, Legal services.

For reasons set forth in the preamble, the Legal Services Corporation amends 45 CFR part 1611 as follows:

PART 1611—FINANCIAL ELIGIBILITY

■ 1. The authority citation for part 1611 continues to read as follows:

Authority: 42 U.S.C. 2996g(e).

■ 2. Revise appendix A to part 1611 to read as follows:

Appendix A to Part 1611—Income Level for Individuals Eligible for Assistance

LEGAL SERVICES CORPORATION 2023 INCOME GUIDELINES *

Size of household	48 Contiguous states and the District of Columbia	Alaska	Hawaii
1	\$18,225	\$22,763	\$20,963
2	24,650	30,800	28,350
3	31,075	38,838	35,738
4	37,500	46,875	43,125
5	43,925	54,913	50,513
6	50,350	62,950	57,900
7	56,775	70,988	65,288
8	63,200	79,025	72,675

LEGAL SERVICES CORPORATION 2023 INCOME GUIDELINES *—Continued

Size of household	48 Contiguous states and the District of Columbia	Alaska	Hawaii
For each additional member of the household in excess of 8, add:	6,425	8,038	7,388

* The figures in this table represent 125% of the Federal Poverty Guidelines by household size as determined by HHS.

REFERENCE CHART—200% OF FEDERAL POVERTY GUIDELINES *

Size of household	48 Contiguous states and the District of Columbia	Alaska	Hawaii
1	\$29,160	\$36,420	\$33,540
2	39,440	49,280	45,360
3	49,720	62,140	57,180
4	60,000	75,000	69,000
5	70,280	87,860	80,820
6	80,560	100,720	92,640
7	90,840	113,580	104,460
8	101,120	126,440	116,280
For each additional member of the household in excess of 8, add:	10,280	12,860	11,820

* The figures in this table represent 200% of the Federal Poverty Guidelines by household size as determined by HHS.

Authority: 42 U.S.C. 2996g(e).

Dated: January 23, 2023.

Stefanie Davis,
Senior Associate General Counsel and Ethics Officer.

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