

Annual Burden Estimates: This request will extend approval of currently approved monitoring forms. Currently approved forms and related

burden can be found here: https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202009-0970-001. Burden estimates for the next 3 years have been updated to reflect trends in

use over the past 3 years. These are based on averages and actual individual requests will vary based on program office need.

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)
New Program Monitoring Forms	1,600	2.5	10	40,000

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; State Plan for Independent Living Instrument and Instructions OMB Control Number 0985-0044

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to the State Plan for Independent Living Instrument and Instructions.

DATES: Submit written comments on the collection of information by April 10, 2023.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find the information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT:

Peter Nye, Administration for Community Living, Washington, DC 20201, (202) 795-7606 or OILPPRACComments@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The Administration for Community Living (ACL) is requesting approval to collect data for the State Plan for Independent Living Instrument and Instructions.

Legal authority for the State Plan for Independent Living (SPIL) is contained in chapter 1 of title VII of the Rehabilitation Act of 1973, as amended by the Workforce Innovation and Opportunity Act ([the Act], Pub. L. 113-128). Section 704 of the Rehabilitation Act requires that, to be eligible to receive financial assistance under chapter 1, "a State shall submit to the Department, and obtain approval of, a State plan containing such provisions as the Department may require." ACL approval of the SPIL is required for states to receive Federal funding for both the Independent Living Services State grants and Centers for Independent Living (CIL) programs. Federal statute and regulations require the collection of this information every three years. The current three-year approval period for the SPIL expires March 31, 2023. The SPIL Instrument is

the template for SPILs; the SPIL Instructions explain the Instrument and give tips about how to draft SPILs.

The Office of Independent Living Programs (OILP) is proposing minor revisions based on OILP and the technical assistance provider revising the Instrument and Instructions to resolve issues that SILCs have reported having with their SPILs, and to increase the Instrument's and Instructions' clarity, conciseness, and precision. For example,

- The revised Instrument and Instructions correct grammatical and punctuation errors.
- The revised Instructions add lines for each core service.
- The revised Instrument and Instructions clarify the definition, and example, of state match.

These updates were recommended by the technical assistance provider and analyzed by all the independent living project officers who work directly with SPILs and the issues that they plan for.

The SPIL is jointly developed by the chairperson of the Statewide Independent Living Council and the directors of the CILs in the state, after receiving public input from individuals throughout the State, and signed by the chairperson of the SILC, acting on behalf of—and at the direction of—the SILC, the director of the designated State entity, and not less than 51 percent of the directors of the CILs in the State. ACL reviews the SPIL for compliance with the Rehabilitation Act and 45 CFR part 1329 and approves the SPIL. The SPIL serves as a primary planning document for continuous monitoring of, and technical assistance to, the state independent living (IL) programs to ensure appropriate planning, financial support and coordination, and other assistance to appropriately address, statewide, needs for the provision of IL services in the state.

The proposed data collection tools may be found on the ACL website for review at <https://www.acl.gov/about-acl/public-input>.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** 87 FR 72487–72488 on November 25, 2022.

There were 35 received during the 60-day FRN.

ACL's responses to these comments are included below.

Comment from	Section	Public comment	ACL response
Stephanie Jensen	Instructions	"Equity and Independent Living Philosophy need to be underlined".	ACL is underlining these terms in the Definitions.
Ann McDaniel	Definitions	ACL supports this definition, so ACL is adding it. ACL agrees with NCIL's assessment that "Independent Living is Independent Living and that too many CILs currently do things that are not consistent with the purpose of Title VII and the IL Philosophy." Therefore, ACL is deleting the statement that "Different centers and different cultures may implement independent living and the philosophy differently."	
	Instructions	Add the following definition of independent living and delete the note "Different centers and different cultures may implement independent living and the philosophy differently."	
	Definitions	"Independent Living means maximizing the ability of people with disabilities to: <ul style="list-style-type: none"> • "Control their own lives; • "Participate in the community; • "Live independently (as opposed to in institutions); and • "Have economic security." 	
Stephanie Jensen	Instructions	"There needs to be a line space after Pacific Islander and before Nonresidential".	ACL supports adding a blank line, so ACL is adding a blank line.
Ann McDaniel	Definitions	Rephrase the "state match" definition to refer to the "Instructions" as opposed to the "Narrative".	ACL is rephrasing in reaction to this comment because the definition means to refer to the Instructions (as opposed to the narrative).
Ann McDaniel	Definitions	Divide the definition of "Unserved and underserved groups or populations" into a definition of "Unserved" and a definition of "Underserved".	ACL believes this division would be too prescriptive. The regulations require the state IL networks to determine (via the SPILs) what is unserved and what is underserved. This issue will require further discussion with state IL networks; ACL will further discuss this issue with state IL networks sometime in the future.
Sandra Fariña	Definitions	Provide specific guidance "as to how the IL Network will determine 'served, unserved, and underserved' populations".	ACL received several comments asking ACL to define "unserved" and "underserved." Instead of adding definitions, ACL is keeping the current definition (which comes from the federal regulations) and is continuing to defer to state IL networks to identify and define unserved and underserved populations. ACL acknowledges that this issue deserves further discussion with the IL community, and ACL will further discuss this issue with the IL community at some later time.
Ann McDaniel	Instructions	Rephrase the public-input requirement to "States are required to gather public input prior to development of the SPIL and feedback/comment prior to its submission and on any proposed revisions to the approved state plan before drafting."	ACL supports this rephrasing because it clarifies that "submission" means submission of the SPIL and clarifies what the public input is supposed to be about.
Ann McDaniel	SPIL Development	Add a SPIL-appeals process (before SPIL submission).	ACL is concerned about this issue but does not want to require appeals processes or written records of objections. Instead, ACL is adding the following statement to the Instructions Section 9 Signatures. "If a required signatory objects to the SPIL, then that required signatory needs to tell the program officer before SPIL submission."
Ann McDaniel	Instructions	Formatting of the SPIL Amendments section needs to be consistent.	ACL agrees, so ACL is formatting this section to be consistent.
Mark Leeper	SPIL Amendments		
Mark Leeper	Section 1: Goals, Objectives and Activities.	Specify that the "goals and objectives should relate to the funding that is available to the IL Network".	ACL thinks that adding this text would be superfluous, so ACL is not adding this text.
Mark Leeper	Section 1: Goals, Objectives and Activities.	"In many states, those creating the SPIL have struggled to make these goals and objectives specific to the funding that the SPIL can directly control"; that has caused confusion and conflicts about CILs reporting "to the DSE and/or SILC on activities that are funded with Part C dollars and that are already being reported in CIL PPRs".	The SPIL is supposed to reflect all the funding for IL in the state, including Part B, Part C, and other funds that pertain to the SPIL outcomes. Therefore, ACL is not revising in reaction to this comment.

Comment from	Section	Public comment	ACL response
Mark Leeper	Section 1: Goals, Objectives and Activities.	"SPIL goals and objectives or workplans should focus on funds available to the state through Part B or other sources and avoid redundant and confusing attention to funds already managed through other mechanisms".	The SPIL is supposed to reflect all the funding for IL in the state, including Part B, Part C, and other funding that supports the goals in the SPIL. Therefore, ACL is not revising in reaction to this comment.
Mark Leeper	Section 1: Goals, Objectives and Activities.	"The SPIL should describe the IL network and offer clear, measurable results of what is done with funding that is available to the network but is not described and monitored by some other process.".	The SPIL is supposed to reflect all the funding for IL in the state, including Part B, Part C, and other funding that supports the goals in the SPIL. Therefore, ACL is not revising in reaction to this comment.
Ann McDaniel	Instructions 1.4 Evaluation	Add the following immediately after "Compliance of CILs receiving Part B funds . . ." " <i>The process for that oversight must be negotiated and included in Section 4.5 of the SPIL.</i> ".	ACL is adding this sentence because ACL often receives questions about this issue.
Ann McDaniel	Instructions 1.5 Financial Plan ...	Clarify that the note refers to deviations from the financial plan "regarding Chapter 1, Part B funds" and that "Deviations of less than 25% may be reported with a technical amendment.".	ACL is adding these revisions because they clarify what requires a substantial amendment and what does not.
Ann McDaniel	Instructions 1.5 Financial Plan ...	In the 1.5 Financial Plan table, delete the struck-through text in the "Non-Federal Funds" cell.	ACL is deleting this struck-through text (because it is unnecessary).
Ann McDaniel	Instructions 1.5 Financial Plan ...	"Instructions for the narrative section should indicate that justification for using more than 30% of the Part B funds for the SILC Resource Plan should be included here.".	ACL is not including such a statement because that the Instrument and Instructions adequately give that instruction elsewhere.
Stephanie Jensen	Instrument 1.5 Financial Plan.	"separate lines for Part B Match, other match, and State funds will make the math easier because a step is eliminated".	ACL agrees with this assessment; this assessment does not make any revision necessary.
Stephanie Jensen	Instrument 1.5 Financial Plan.	"it is good that it is clear that the line for Innovation and Expansion Funds . . . cannot be \$0.".	ACL agrees with this assessment; this assessment does not make any revision necessary.
Ann McDaniel	Instructions 2.1 Narrative	In 2.1 Narrative, "Specify what entities, if any, other than CILs are providing IL services in the state and how the DSE ensures such services are consumer controlled . . .".	ACL is not adding such a statement because entities other than CILs that provide IL services are not required to be consumer controlled.
Ann McDaniel	Instructions 3.1 Existing Centers	Add "a method . . . to indicate which counties are . . . served, unserved, and underserved . . .".	ACL is not adding a method because the state IL network is supposed to determine (according to its standards) which counties are served, unserved, and underserved.
Sandra Fariña	4.1 DSE Responsibilities.	"Require all responsible parties listed within the SPIL to agree to the assigned data collection and defined responsibilities to promote compliance with the ILS PPR.".	The terms and conditions of grants to CILs require them to submit program performance reports to the SILC. If a state IL network wants and/or needs more assurance of this kind, then that state IL network can impose this kind of assurance. (The SPIL is not supposed to be an assurance document.) Therefore, ACL is not adding something in reaction to this comment.
Stephanie Jensen	Instructions 4.4 Grant Process & Distribution of Funds.	Italicize "Describe the processes, policies, and procedures . . ." and the following bullet points.	ACL is italicizing this text.
Stephanie Jensen	Instructions 4.5 Oversight Process for Part B Funds.	"The oversight process for the DSE" needs to be in the same font size as the rest of the subsection.	ACL is correcting this error.
Stephanie Jensen	Instructions 4.5 Oversight Process for Part B Funds.	The first italicized text needs to be on its own line	ACL is correcting this error.
Stephanie Jensen	Instructions 4.5 Oversight Process for Part B Funds.	"Other oversight activities" needs to be its own bullet point.	ACL is correcting this error.
Cheryl Peabody ...	Instructions 5.2 SILC Resource Plan.	"detailed instructions" on "how to acknowledge I&E funds allocations reporting in the [SILC] Resource Plan" would be helpful.	ACL means to offer more guidance on how to report I&E funds; such guidance would be outside the scope of the SPIL Instrument and Instructions. Therefore, ACL is not adding instructions to the SPIL Instrument and Instructions.
Stephanie Jensen	Instructions 5.2 SILC Resource Plan.	"It is good that there is a place to describe the SILC authorities that the SILC will be engaging in during the SPIL. Section 5.2 seems to be a good place.".	ACL agrees with this comment and understands that it requires no revision, so ACL is not revising in reaction to this comment.

Comment from	Section	Public comment	ACL response
Ann McDaniel	Instructions 5.2 SILC Resource Plan.	In 5.2 SILC Resource Plan, rephrase the “Narrative” instruction to “Provide a brief description of how the SILC Authorities will be conducted by the SILC during . . .”.	ACL agrees that this rephrasing is more accurate and easier to understand.
Sandra Fariña	5.2 SILC Resource Plan.	“Describe what process(es) will be used to disburse funds for the SILC Resource Plan . . .”.	Adding such description would be outside the SPIL’s proper scope: The DSE and SILC are supposed to choose processes that comply with state policies.
Sandra Fariña	5.2 SILC Resource Plan.	“Provide guidance on acceptable forms of resource development that the SILC may engage in.”.	ACL is adding a statement about this issue and a citation of the regulatory requirement.
Ann McDaniel	Instrument 5.2 SILC Resource Plan.	Add a chart of authorities that Section 705(c)(2) of the Act allows the SILC to elect to engage in.	ACL is not adding such a chart because the information that this chart would request is adequately requested elsewhere in the SPIL.
Ann McDaniel	Instructions 5.3 Maintenance of SILC.	In 5.2 SILC Resource Plan, “provide a list of the Authorities with space for the SILC to mark which they are electing to conduct . . .”.	ACL agrees that adding this list would be helpful; ACL is adding it as a list as opposed to a chart.
Ann McDaniel	Instructions 9 Signatures.	“[clarify] that a signature space be included for every CIL eligible . . .”.	ACL is adding this clarification because it is helpful.
Sandra Fariña	[none in particular].	“Identify opportunities for the SILC and its IL partners to engage in training and technical assistance . . .”.	ACL requires all IL networks to do training and technical assistance; that is not supposed to be part of the SPIL Instrument and Instructions. Therefore, ACL is not adding something in reaction to this comment.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows: 56 Statewide Independent Living Councils (SILCs) will respond to the requirement for a SPIL every three years. Each state’s, outlying area’s, or the District of

Columbia’s SILC will take approximately 60 hours to develop the SPIL for a total of approximately 3,360 hours. This estimate is based on amounts of time SILCs have reported previously spending to complete the SPIL. ACL does not expect the changes

to the Instrument and Instructions to take more or less time than the currently approved information collection. Therefore, there is no change to the estimated burden.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Statewide Independent Living Councils	56	1	60	3,360
Total	56	1	60	3,360

Dated: March 3, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Babson Diagnostics, Inc., for the Babson Diagnostics aC19G1, and Twist Bioscience Corporation for the SARS-CoV-2 NGS Assay. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by each Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The Authorization for the Babson Diagnostics aC19G1 is revoked as of February 14, 2023. The Authorization for the SARS-CoV-2 NGS Assay is revoked as of February 14, 2023.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 3216, Silver Spring, MD 20993-0002, 301-796-0311 (this is not a toll-free number).