

Information Collection Request

Reinstatement with Change

Sealant Efficiency Assessment for Locals and States (SEALS)
0920-1289

Supporting Statement: Part A

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October 11, 2023

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REFERENCES

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1. The Public Health Service Act (42 U.S.C. 301; and 42 U.S.C 247b–14 Oral health promotion and disease prevention)
2. Invite to participate in SEALS
 - 2a. Screenshots of entry forms from SEALS User Manual
 - 2b. Paper data collection form
 - 2c. Screenshot of default cost values
3. 60-Day Federal Register Notice
4. Human Subject Documentation non-research determination
5. Part I worksheet
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Goal of the project: To lower caries rates among at-risk children by increasing the efficiency of local school sealant programs, which in turn will lead to more children receiving sealants to prevent oral health disease.

Intended use of the resulting data: The data will be used to generate school sealant program (SSP) efficiency performance measures (e.g., cost per averted cavity). Local SSPs and state oral health programs can use this information to monitor progress and increase efficiency, document return on

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests a three-year OMB approval for a reinstatement with change to collect state data from ongoing local school sealant programs nationwide. CDC is authorized to collect the information under the Public Health Service Act, Title 42, Section 247b–14, Oral health promotion and disease prevention; and the Public Health Service Act, Title 42, Section 301 (Attachment 1).

By age 19, 67% of US adolescents living in poverty have experienced tooth decay and 27% have at least one decayed tooth needing treatment¹. Untreated tooth decay will not resolve and can cause pain, infection, and difficulties in learning², which is associated with lower school attendance and grades³. More than 34 million school hours are lost annually due to unplanned dental visits for acute care needs⁴.

Much of this decay could have been prevented with dental sealants – thin coatings that, when painted on the chewing surfaces of the back teeth (molars), can prevent tooth decay for many years. About 90% of cavities in the permanent teeth occur in molars⁵. Once applied to the molars, sealants protect against 80% of cavities for 2 years and continue to protect against 50% of cavities for up to 4 years⁶. Sealant prevalence among low-income

children, who often lack access to clinical dental care, is low; over 60% of low-income children have not received the benefits of sealants⁷.

School sealant programs (SSPs) are an effective strategy to increase sealant prevalence among low-income children⁶. Although the Community Preventive Services Task Force (Task Force) recommends SSPs based on strong evidence of effectiveness and cost savings when delivered to children at high risk for tooth decay⁶, only 15 states have SSPs in the majority of their low-income schools (i.e., >50% of students enrolled in the free and reduced lunch programs)⁸.

Because there was limited information on both the cavity risk status of children served by SSPs and the retention rate of sealants the programs placed in children (a retained sealant is 100% effective⁹), CDC asked the 20 states it funded for school sealant programs (under State Actions to Improve Oral Health Outcomes CDC-RFA-DP18-1810) to voluntarily provide information to estimate the SSP benefit in their state at least once during the 5-year funding period. CDC asked them about children's cavity risk, one-year sealant retention rate (when the sealant remains fully intact over tooth surface), and sealant program services delivered.

By analyzing this information, CDC estimated several summary measures including the annual cavity attack rate and averted cavities attributable to SSPs in each funded state. These findings were used to develop an economic model to estimate the cost-effectiveness of SSPs for the US, and it was published in a peer-reviewed article¹⁰. The Community Preventive Services Task Force also used CDC's findings on the caries risk of children served by SSPs to document the generalizability of their finding that SSPs are cost-saving when delivered to children with high cavity risk. This analysis was also published in a peer-reviewed journal¹¹.

Data on SSP benefits alone at the state level, however, are insufficient to evaluate the efficiency of SSPs. Little is known about school sealant program delivery logistics, resource costs, or the quantity of resources used per unit of service or per averted cavity¹¹. The previously mentioned economic model on the cost-effectiveness of SSPs could find no recent studies on SSP cost in the US and relied on the findings from four studies, all published before 2001¹⁰. A systematic review of economic evaluations of SSPs conducted by the task force further found wide variation in reported cost per child, ranging from \$33 to \$163⁶. Information on the cost and efficiency of SSPs could help these programs become more efficient and provide more services per dollar in their budget.

CDC developed an optional web-based data collection and analysis tool, called the Sealant Efficiency Assessment for States and Locals (SEALS), so that states could more easily enter information for CDC's

analysis and to generate reports to monitor their SSP programs. Several local SSPs and state sealant coordinators in states not funded by CDC have requested to use SEALS developed for funded states. Therefore, CDC proposes to formally invite all states, territories, and tribes (herein referred to as “states”) to participate so it can benefit all interested states’ chronic disease prevention efforts. This will also give CDC more uniform and consistent data to analyze over time, and all of the measures will be calculated against the same criteria.

2. Purpose and Use of the Information Collection

Sealant data use are intended to improve program planning, implementation, and resource allocation by CDC and states, and increase SSP reach and sustainability. CDC will use these SSP-level data to develop feasible efficiency benchmarks and to identify practices contributing to efficiency. Information on individual SSP cost and efficiency could help states better monitor the SSPs they fund, which in turn could result in increased SSP efficiency and ultimately to more children being sealed per dollar spent. Additionally, this information will provide critical information to:

1. SSPs on their program efficiency and relative efficiency to other SSPs;
2. State oral health programs to monitor the relative performance of SSPs and to identify the most efficient programs within their state; and,
3. CDC to monitor funded states and to conduct a study to establish feasible benchmarks for SSPs, and to identify practices contributing to SSP efficiency.

The reasons that local SSP’s share their data with state oral health programs varies by state. These include: a strong relationship built on past collaborations; to gain access to public schools; and to receive state funding.

CDC has developed a web application for the electronic entry and analysis of SSP data called SEALS. An invitation to participate is sent to the funded and non-funded states, territories, and tribes (Attachment 2). State oral health programs give password-protected access to SSP administrators so they can enter data into SEALS, rather than using paper forms. Entering data directly into the electronic database reduces duplicate data entry, decreases errors, and saves time (Attachment 2a). For SSPs to access SEALS, the state oral health program must first set up an account for each SSP. SSPs may create a user account for additional SSP staff (under the Add User tab).

At the beginning of each school year, SSPs electronically enter a list of schools they plan to serve (Add Schools), information about their program delivery logistics (Program Options), and per unit resource costs (Cost Options). Data suggests that one SSP typically serves 20 schools. At each school event, SSPs enter information about resource use, children's risk for tooth decay, and delivered services (Add Event).

Information collected at each school can be entered electronically onsite or collected on paper form (Attachment 2b) and entered electronically at a later date. Many SSPs already collect this school event data for billing purposes; these programs can export this information from their billing software and upload it as batch data into SEALS.

At the end of the school year, SSPs enter administrative costs (e.g., office supplies, rent, computers, which is one field entry on the Cost Options tab) electronically, and within 9 to 15 months after first visiting the school, they enter information about sealant retention (one field entry under Program Options tab). Effectiveness of resin-based sealants is directly tied to retention, in that a retained sealant is 100% effective at preventing cavities. Because of this, many SSPs sample a few children for retention when they visit the school the next year to deliver services to new students.

Three levels of users (local SSP, state, and CDC) can generate reports with performance measures (Attachment 2c) calculated from data input by the local SSPs. Each funded state is requested to provide CDC with data via SEALS for one school year at least once during the five-year funding period. CDC uses the information to assist funded states to monitor SSP performance and provide local SSPs with information to improve performance and efficiency. State reports include information aggregated across all local SSPs and for each SSP. States can rank the performance of SSPs for each performance measure.

3. Use of Improved Information Technology and Burden Reduction

CDC developed a web application, called SEALS, which automates the analysis of SSP data to estimate SSP efficiency measures (cost per service or benefit) for each state and also for each SSP.

SEALS is a easy-to-use data collection, management, and analysis system hosted and maintained by CDC. To reduce respondent burden, SEALS provides a choice of manually entered costs or default values for the costs of several types of resources, such as the costs of equipment and instruments, so that the respondent does not need to determine the original cost or amortize the cost of durable items. Default equipment cost and useful life

estimates were obtained from various manufacturers and vendors; hourly labor costs obtained from Bureau of Labor Statistics; and costs of supplies obtained from a panel of SSP experts. The data collection at the site is through a paper form (50%) or electronically (50%), directly into SEALS. The data is transmitted to CDC electronically (100%).

In addition, SEALS automatically calculates performance measures for 1) local SSPs, 2) state oral health departments using aggregated data from local SSPs, and 3) CDC using aggregated data from all local participating SSPs. SEALS provides information to all three levels of users without duplicate data entry. SEALS technology reduces the costly burden states and local SSPs would have to do to analyze these data about their programs and enables uniform data collection and analysis so that the measures are directly comparable among programs in their same state and across all states. The methodologies used in SEALS are designed to estimate SSP cost and impact with the minimal amount of data necessary to obtain accurate estimates, and these methodologies have been peer reviewed and published^{12, 13}.

4. Efforts to Identify Duplication and Use of Similar Information

The data collected do not duplicate data collected by other federal agencies that fund SSPs: HRSA primarily by funding FQHCs, and CMS by reimbursing programs for sealants (fee for service).

The current sealant performance measures endorsed by the National Quality Forum and used by HRSA and CMS collect information about the utilization of services in a clinical setting (i.e., percentage of children at elevated risk for tooth decay receiving a sealant on a permanent molar from a dentist) and not in school settings where dental hygienists typically provide and bill for services. At present, there is little available information to evaluate school sealant program efficiency, and published estimates of the cost of resources used by school sealant programs vary widely. Data collection allows CDC to measure both the impact of sealant programs and their associated costs.

A team of nine stakeholders convened by CDC reported that they are unaware of any other similar SSP data collected across programs and states. CDC held a series of conference calls with the nine stakeholders. In addition, state sealant coordinators and local school sealant program administrators in attendance at the National Oral Health Conference in 2014, who viewed the data collection tool, indicated no existence of a similar collection or tool.

5. Impact on Small Businesses or Other Small Entities

A 2014 report funded by the CDC and prepared by the Children's Dental Health Project included information about the type of entities that provide sealants in school settings¹⁴. Of the 664 SSPs interviewed between 2011 and 2013, this report found that approximately half of SSPs are small entities, including local health departments, nonprofits, and for-profit practices; 17% are FQHCs. Many of these entities have to report sealant data to the federal government, including Medicaid, and to state oral health programs. SEALS improves reporting accuracy and reduces the burden on state programs.

If respondents opt to select default values, the only original data collection required for this collection are the quantity of resources used at each school (i.e., labor hours and mileage) and child-level data of caries risk and services delivered. Information on children's caries, risk status, and services delivered can be downloaded from billing software and then uploaded into SEALS. Nearly 100% of services are billed to private insurance or the federal government.

6. Consequences of Collecting the Information Less Frequently

This is a convenience sample of SSPs requested to input data for at least one school year in a five-year period. Data must be entered for all schools served by an SSP during the same year to get accurate estimates of costs. If information about services provided were only collected for 50% of students, then fixed costs would be overestimated – twice the actual cost. In addition, allowing SSPs to only report on select schools could result in selecting only those schools in which the highest-risk children were seen, resulting in inflated estimates of averted cavities.

Collecting data less frequently could result in inefficient and wasteful practices not being detected or being detected after waste has accumulated. As the goals of this project are to establish feasible efficiency benchmarks and best practices, it is important to have accurate, complete, and unbiased data.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances relating to the guidelines of 5 CFR 1320.5, and the project fully complies with the regulation.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE

A 60-day Federal Register Notice (Attachment 3) was published in the *Federal Register* on, June 5, 2023, vol. 88, No. 107, pp 36583–36584 to obtain comments from the public and affected agencies. CDC received no comments.

Part B: CONSULTATION

The methodology to estimate SSP resource costs with minimal data were developed by a volunteer team consisting of academic economists, state sealant coordinators, and local SSP administrators. The consultants provided information on necessary resources, costs, and the useful lives of durable items. Critical resources were identified with per unit costs not likely to vary by SSP. For example, consultants knew that most SSPs buy their portable dental equipment from one of two manufacturers, therefore CDC contacted those manufacturers to obtain information on price and useful life to estimate the annual cost.

Consultation with state sealant coordinators occurs several times a year by the CDC project officer through monthly calls and mid-year and end-of- year progress reports for the cooperative agreement. There have not been any changes in burden and data collection.

State programs have used this information to monitor progress and increase efficiency, and increase their reach. CDC has used this information to identify feasible benchmarks for SSPs and identify best practices contributing to SSP efficiency.

Consultants providing information to estimate SSP resource costs with minimal data (2018)			
Name	State	Affiliation	Position/Contact information
Terri Chandler RDH	NV	Future Smile	SSP Administrator 702-799-1204
Ashlei McTrusty RDH	WI	Northern Health Centers, Inc.	SSP Administrator 888-834-4551 AshleiM@nhcmedden.com
Nancy Rublee RDH	WI	Price County HHS Department	SSP Administrator 715-339-3054 nancy.rublee@co.price.wi.us
Sharon Logue RDH	VA	VA Department of Health	State Sealant Coordinator 804-864-7775
Clare Larkin RDH	MN	MN Department of Public Health	State Sealant Coordinator 651-201-4230 clare.larkin@state.mn.us
Jaelyn Seefeldt RDH	ND	ND Department of Health	State Sealant Coordinator 701-328-4645

			jjseefeldt@nd.gov
Matt Crespin RDH	WI	Children’s Health Alliance	Sealant Coordinator 414-337-4562 mcrespin@childrenswi.org
Kari Jones, PhD	FL	QHR	Economist 770-598-4780 kjones@qhr-econ.com
Joan O’Connell, PhD	CO	University of Colorado	Economist 303-724-1459 joan.oconnell@cuanschutz.edu

In 2017-2018, eight states funded by CDC piloted SEALS. Representatives from these states reviewed the SEALS user manuals and provided feedback on the electronic interface and length of time to enter data into SEALS. CDC learned important information, such as that SSPs typically record information on children’s caries risk status and services delivered in their billing software, and thus updated SEALS’ ability to utilize the information and prevent duplicated collection.

Consultants providing feedback on SEALS interface (2018)			
Name (State Sealant Coordinator)	State	Affiliation	Contact information
Elizabeth Dowd RDH	CT	CT Department of Public Health	860-509-8000
Jorge Bernal DDS	GA	GA Department of Public Health	404-651-5493 jorge.bernal@dph.ga.gov
Stephanie Chickering RDH	IA	IA Department of HHS	515-240-9819 stephanie.chickering@idph.iowa.gov
Michele Mieses RDH	KS	KS Department of Health and Environment	785-368-8264
Clare Larkin RDH	MN	MN Department of Public Health	651-201-4230 clare.larkin@state.mn.us
Seymone Powell RDH	MS	MS State Department of Health	601-576-7400
Elizabeth Girolami RDH	NY	NY State Department of Health	518-402-7500
Veronica DeFonseca RDH	RI	RI Department of Health	401-222-5960

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC's Information Systems Security Officer has reviewed this submission and has determined that the Privacy Act does not apply. Activities do not involve the collection of personally identifiable information.

CDC hosts the data collection tool, SEALS, a Web-based enterprise application maintained on a secure, DHHS/CDC server. It has a Certification and Accreditation and an Authority to Operate. SEALS is an authenticated access data application so only designated users can enter data for state programs. States designate local SSP users and create an authenticated password. The password and other information kept by CDC are private and secure to the extent permitted by law. SEALS administrators cannot view user password credentials.

CDC will maintain information collected in SEALS so that states have historical school sealant program efficiency data. CDC will retain and destroy records in accordance with the applicable CDC Records Control Schedule.

Information from each school event, including number of children screened, number of children sealed, and number receiving prophylaxis is entered in aggregate form. If states choose to ask their programs enter child-level data for their own purposes, programs are required to give each child a unique identification number to maintain sensitive data. It is the responsibility of the local programs and states to maintain and protect data. CDC only includes aggregate and summary information in reports and does not include information that may identify respondents.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

CDC's Institutional Review Board (IRB) determined that this project does not constitute research with human subjects as defined by the US Code of Federal Regulations (45 CFR 46.102) (Attachment 4)

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

A description of the estimated annualized burden hours is explained for each level of user below:

State Sealant Administrator

CDC estimates that SSPs in 18 states (14 funded and 4 non-funded states) will provide data for one school year within the next 3 years.

- The estimate of 14 funded states participating was obtained by multiplying the number of states funded by CDC for SSPs in the 2019–2023 funding period (=19) by the participation rate in the 2013–2018 funding period (0.76, 13 of 17 funded states).
- The estimate of 4 non-funded states was based on previous inquiries from non-funded states about gaining access to SEALS.

Once, at the beginning of the school year, the state sealant administrator will set up accounts for each SSP and 1 user per SSP (Add Program and Add User). It is estimated that this will take each state administrator 45 minutes (9 SSPs per state*5 minutes per entry).

- The estimate of 9 SSPs per state was based on the average number of SSPs in states funded by CDC from 2013 to 2018.
- The estimate of 5 minutes to add an SSP (2 minutes) and to add an SSP user (3 minutes) was obtained from input provided by 2 state sealant administrators, 3 local SSP administrators and 1 CDC employee who piloted SEALS in 2017/2018.

Local SSPs

It is estimated that 162 local SSP administrators will provide data (9 SSPs per state * 18 states). Once, at the beginning of the year, each SSP will take 43 minutes (3 minutes to add one user + (2 minutes to add each school * 20 schools)) to input information into SEALS (Add User and Add School).

- The estimate of 3 minutes to add a user and 2 minutes to add a school were obtained from input from 3 local SSPs and 1 CDC employee who piloted SEALS in 2017/2018. The estimate of 20 schools was based on the average number of schools served by an SSP in states funded by CDC from 2013–2018.

Once during the school-year, each of the 162 SSPs will take 46 minutes to input information on program logistics and resource costs per unit (Program Options and Cost Options).

- The estimate of 46 minutes was obtained from 3 SSP administrators who piloted SEALS in 2017/2018.

At each of the 20 schools, the local SSP will take 21 minutes to input information on units of resources used, children’s caries risk, and services delivered (Add Event).

- The estimate of 21 minutes was obtained from 3 SSP administrators.

Table 12a. Estimated Response Burden Table (Hours)

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State Sealant Administrator	State and Program Administrator Screens - Add User and Add Program	18	1	45/60	14
SSP Local Administrator	State and Program Administrator Screens - Add User and Add School	162	1	43/60	116
	State and Program Administrator Screens - Program Options and Cost Options	162	1	46/60	124
	Child Aggregate Screens Add Event or Child Detail Screens SEALS Event Data - Add Event	162	20	21/60	1,134
Total					1388

12b. Annualized Cost to Respondents

Dental hygienists are the most likely respondents, as they are typically the local school sealant program administrators. The average hourly wage for dental hygienists (\$35.91) was obtained from the U.S. Department of Labor, Bureau of Labor Statistics. The total cost to respondents is \$49,835.90 as summarized below in Table A.12-B.

Table 12b. Annualized cost to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage Rate	Total Cost
State Sealant Administrator	State and Program Administrator Screens - Add User and Add Program	18	1	45/60	\$35.91	\$484.79
SSP Local Administrator	State and Program Administrator Screens - Add User and Add School	162	1	43/60	\$35.91	\$4,169.15
SSP Local Administrator	State and Program Administrator Screens - Program Options and Cost Options	162	1	46/60	\$35.91	\$4,460.02
SSP Local Administrator	Child Aggregate Screens Add Event or Child Detail Screens SEALS Event Data - Add Event	162	20	21/60	\$35.91	\$40,721.94
Total						\$49,835.90

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs. SEALS requires no special hardware or software and is free to states and SSPs.

14. Annualized Cost to the Federal Government

The average annual contractor cost for this data collection is \$40,000 per year for a three-year total of \$120,000. Additional annual costs include personnel costs of federal employees involved in program management, technical assistance for SEALS, and analysis. The annual staff cost is estimated at \$22,810.

Exhibit A14-A presents the two types of costs to the government that will be incurred: (1) external contracted data collection and analyses and (2) government personnel.

Table A14-A. Estimated Annualized Federal Government Cost Distribution

Type of Government Cost	Annualized Cost
SEALS website maintenance (contractor)	\$40,000
Federal Staff	\$11,405
GS-12 health scientist at 5% FTE	\$4,367
GS-14 health economist at 5% FTE (Benchmarking study)	\$7,038
Total	\$62,810

15. Explanation for Program Changes or Adjustments

The CDC requests a three-year OMB approval for a reinstatement (Expiration date 03/31/2023) with change (OMB Control Number: 0920-1289). The change is the addition of collecting race/ethnicity data according to OMB standards. To advance health equity, addressing social determinants of health and improving diversity, equity, inclusion, accessibility, and belonging, the collection of race/ethnicity is crucial.

Driving factors behind negative social determinants of health—such as economic policies and systems, social norms, systemic racism, and climate change—have negatively affected the health and health outcomes of

groups including, but not limited to African American/Black, American Indian or Alaska Native, Asian, Hispanic, or Latino, and Native Hawaiian or other Pacific Islander people.

The reinstatement request occurred because of delays by program to prepare the OMB package. There were no changes to burden.

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation:

CDC will use multivariate regression to identify factors beyond a SSPs control that can predict performance. Hypothesized factors include the state Dental Practice Act, urbanicity (% of served schools that are in rural counties), and SSP size. Once factors are identified, CDC will partition data by these factors and examine distribution of data (Table Shell 1),

Table Shell 1

	Performance Measure				
	Resource cost per child sealed	Resource cost per tooth sealed	Clinical labor time per child sealed	Clinical labor cost per child sealed	Resource cost per averted cavity
Quintiles					
20%					
40%					
Median					
60%					
80%					
100%					
Mean					
Mode					

Results of the study will be disseminated to states, SSPs and other stakeholders through reports, briefings, presentations at professional meetings, and publication of manuscripts in peer-reviewed journals. It is anticipated that the results of this project will be developed into several scientific and non-scientific reports.

Table A16-B. Project Time Schedule

Estimated Time Schedule for Project Activities

Activity	Timeline
State administrators set up accounts for SSPs	Beginning of school year
SSPs enter program and cost information	Beginning of school year
SSPs enter school sealant data	Once per school in one school year
Data validation	Ongoing for 2 years, CDC can do real-time monitoring as all data are entered electronically and can be viewed by CDC.
Announce that SEALS is available to non-CDC funded states	1 month after OMB approval
Publication	Within 30-36 months after data analysis

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will not be displayed on all information collection instruments to make the most efficient use of stockpiled forms.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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