

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**HELUNA HEALTH MAY NOT HAVE USED
CALIFORNIA'S CDC COVID-19 FUNDS
IN ACCORDANCE WITH AWARD
REQUIREMENTS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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**Amy J. Frontz
Deputy Inspector General
for Audit Services**

**July 2024
A-04-22-02037**

Office of Inspector General

<https://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: July 2024

Report No. A-04-22-02037

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

Congress approved COVID-19 funding to the Centers for Disease Control and Prevention (CDC) for its Epidemiology and Laboratory Capacity (ELC) program to provide support for response activities. CDC used its ELC cooperative agreement (award) to distribute significant amounts of its COVID-19 funding to existing recipients, including Public Health Foundation Enterprises, doing business as Heluna Health (Heluna Health).

COVID-19 has created extraordinary challenges for the delivery of health care and human services to Americans. As the oversight agency for HHS, the Office of Inspector General (OIG) oversees HHS's COVID-19 response and recovery efforts. This audit is part of our COVID-19 response strategic plan.

Our objective was to determine whether Heluna Health used its CDC COVID-19 funding in accordance with award requirements.

How OIG Did This Audit

Our audit covered \$588 million in CDC ELC COVID-19 expenditures that Heluna Health claimed between March 2020 and September 2021. We selected a stratified random sample of 146 line items totaling \$561.7 million. We sent questionnaires to Heluna Health, interviewed officials from CDC and Heluna Health, and reviewed and analyzed documentation we received to support each sample item.

Heluna Health May Not Have Used California's CDC COVID-19 Funds in Accordance With Award Requirements

What OIG Found

Heluna Health may not have used its COVID-19 funding in accordance with award requirements. For 139 of the 146 sample items we reviewed, costs charged to the award were generally in compliance with award requirements; however, 3 were not. Specifically, for three sample items, Heluna Health did not maintain adequate documentation to support the costs claimed and some costs were not consistent with award purposes. These errors occurred because Heluna Health did not require the California Department of Public Health (CDPH) to submit underlying support documentation for costs claimed for reimbursement. As a result, we found that Heluna Health claimed \$3,585,834 in unallowable costs.

In addition, for four sample items, Heluna Health disbursed advances to CDPH for start-up costs to local health jurisdictions (LHJs). Because adequate documentation to support these advances was not provided, we have no assurance these costs totaling \$366,850,858 were used specifically to support the ELC COVID-19 award.

What OIG Recommends and Heluna Health Comments

We recommend that Heluna Health (1) refund \$3,585,834 to the Federal government; (2) develop and implement a policy that requires CDPH to provide support documentation for costs; and (3) work with CDC to determine the allowable portion of \$366,850,858 related to LHJ start-up costs and refund to the Federal Government any unallowable amount. The full list of recommendations is contained within the report.

In written comments to our draft report, Heluna Health did not concur with our recommendations. Instead, Heluna Health described the actions it has taken or will take to address our three recommendations. Specifically, Heluna Health stated it will (1) provide supporting documentation to and work with CDC to explain the allowability of the costs we determined unallowable; (2) develop and implement a documentation policy to address allowability and allocability of costs; and (3) work with CDC to explain the costs covered by the advances to the LHJs.

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INTRODUCTION

WHY WE DID THIS AUDIT

Congress approved five COVID-19 appropriation bills to fund HHS's pandemic response efforts, including funding to the Centers for Disease Control and Prevention (CDC) to provide support for core public health response activities, such as epidemiology, surveillance, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities.¹ CDC used its Epidemiology and Laboratory Capacity (ELC) cooperative agreement (award) to distribute significant amounts of its COVID-19 funding to existing recipients, including Public Health Foundation Enterprises, doing business as Heluna Health.^{2, 3 4}

In the State of California, the California Department of Public Health (CDPH) designated a bona fide agent, Heluna Health, to manage its ELC COVID-19 funding. Heluna Health subawarded ELC COVID-19 funds back to CDPH, which then contracted with local health jurisdictions (LHJs) to assist with local COVID-19 response efforts. Federal regulations state that when significant parts of a Federal program are passed through to subrecipients, a weak monitoring system for subrecipients would indicate higher risk.⁵ In addition, the State of California Auditor's Office designated CDPH's management of COVID-19 funds as high-risk.⁶ Because of the funding relationships within the state, as well as the State Auditor's high-risk designation, we selected for audit CDC's COVID-19 funding to California.

COVID-19 has created extraordinary challenges for the delivery of health care and human services to Americans. As the oversight agency for HHS, the Office of Inspector General (OIG)

¹ The appropriation bills included (1) the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); (2) Families First Coronavirus Response Act (P.L. 116-127); (3) CARES Act (Coronavirus Aid, Relief, and Economic Security Act) (P.L. 116-136); (4) Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); and (5) the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (P.L. 116-260).

² A cooperative agreement is a financial assistance support mechanism used when there will be substantial Federal programmatic involvement. Substantial involvement means that the awarding office program staff will collaborate or participate in project or program activities as specified in the Notice of Award.

³ Heluna Health is the bona fide agent for the California Department of Public Health (CDPH). A bona fide agent is an organization identified by a public health department as eligible to apply for and manage grants.

⁴ Throughout the report we will refer to Public Health Foundation Enterprises as Heluna Health.

⁵ 45 CFR 75.519(b)(1)(ii)

⁶ California State Auditor Report 2020-612, *California Department of Public Health: It Could Do More to Ensure Federal Funds for Expanding the State's COVID-19 Testing and Contact Tracing Programs Are Used Effectively*, April 2021. Available online at <https://www.auditor.ca.gov/pdfs/reports/2020-612.pdf>. Accessed on Jan. 16, 2024.

oversees HHS's COVID-19 response and recovery efforts. This audit is part of OIG's COVID-19 response strategic plan.⁷

OBJECTIVE

Our objective was to determine whether Heluna Health used its CDC COVID-19 funding in accordance with award requirements.

BACKGROUND

COVID-19 Epidemiology and Laboratory Capacity Program

The goal of the ELC program is to reduce illness and related deaths caused by a wide range of infectious disease threats, such as Zika, Ebola, and COVID-19. CDC awards funds to 64 recipients each year to strengthen public health program growth while providing the flexibility needed to address emerging infectious disease issues.⁸ In the event of a public health crisis such as the COVID-19 pandemic, CDC makes supplemental funds available through the ELC award.

The ELC COVID-19 funding was intended to accomplish the following:

- support jurisdictions in conducting surveillance to detect transmission;
- establish and monitor activities related to COVID-19 in the areas of epidemiology, laboratory, and informatics;
- strengthen state and local public health laboratory preparedness and response capabilities;
- provide resources to state, local, and territorial health departments in support of a broad range of COVID-19 testing and epidemiologic surveillance-related activities; and
- support and oversee expanded testing capacity for COVID-19, including the ability to process, manage, analyze, use, and report the increased data produced.

⁷ HHS-OIG's COVID-19 response strategic plan and oversight activities can be accessed at [HHS-OIG's Oversight of COVID-19 Response and Recovery | HHS-OIG](#).

⁸ The 64 ELC recipients include all 50 States, several large metro areas, and U.S. territories and affiliates.

Heluna Health

Heluna Health, a California non-profit corporation, became the bona fide agent for CDPH to receive the CDC ELC award during the 2003 SARS outbreak. Therefore, CDC awarded California's ELC COVID-19 funding to Heluna Health. As CDPH's bona fide agent, Heluna Health was the prime recipient of CDC's ELC COVID-19 funding and had the following responsibilities for this ELC funding:

- submitting a grant application to CDC,
- ensuring compliance with award requirements,
- providing overall coordination of ELC program implementation,
- providing general administrative functions and support, and
- collaborating with CDPH.

Heluna Health subawarded ELC COVID-19 funding to CDPH to assist in accomplishing the goals and objectives of the ELC COVID-19 awards, including addressing gaps in areas such as the public health workforce, laboratory testing, surveillance, and contact tracing at local levels. CDPH subsequently allocated funds to LHJs through a contractual arrangement to support COVID-19 testing and epidemiologic surveillance activities.

According to the contractual arrangements between CDPH and LHJs, to obtain reimbursement for costs incurred, LHJs must provide invoices (statements of expenditures) to CDPH. To obtain reimbursement, CDPH submitted these statements of expenditures with spreadsheets to Heluna Health summarizing the costs incurred for the billing period, to include LHJs.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$588 million in CDC ELC COVID-19 expenditures Heluna Health claimed between March 2020 and September 2021 (audit period). We selected a stratified random sample of 146 line items totaling \$561.7 million.⁹ We sent questionnaires to Heluna Health officials related to their processes, procedures, and controls; interviewed officials from CDC and Heluna Health; and reviewed and analyzed documentation we received to support each sample item.

We used CDC's COVID-19 ELC award requirements as the basis of our review and 45 CFR Part 75 to assess compliance with monitoring activities and allowable costs.

⁹ Our sample selection consisted of sample items taken from five strata. See Appendix B for information on our sample.

For each of the 146 sample items, we obtained and reviewed documentation to support the costs charged to the Federal award. For sample items that included multiple charges, we judgmentally selected a variety of cost categories within each sample item to ensure we reviewed all cost categories.

When determining the allowability of sample items, we considered the various flexibilities brought on by the COVID-19 pandemic and the need for public health agencies to respond swiftly. For example, we considered charges for supplies and hand movers to transport items around COVID-19 testing sites allowable because they were necessary for the performance of the award.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Appendix A contains the details of our audit scope and methodology and Appendix B contains the details of our statistical sampling methodology.

FINDINGS

Heluna Health may not have used its COVID-19 funding in accordance with award requirements. For 139 of the 146 sample items we reviewed, costs charged to the award were generally in compliance with award requirements; however, 3 were not. Specifically, for three sample items, Heluna Health did not maintain adequate documentation to support the costs claimed and some costs were not consistent with award purposes. These errors occurred because Heluna Health did not require CDPH to submit underlying support documentation for the costs claimed for reimbursement. As a result, we found that Heluna Health claimed \$3,585,834 in unallowable costs.

In addition, for four sample items, Heluna Health disbursed advances to CDPH for start-up costs to LHJs. Because adequate documentation to support these advances was not provided, we have no assurance these costs totaling \$366,850,858 were used specifically to support the ELC COVID-19 award.

FEDERAL REQUIREMENTS

The 2019 Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases Notice of Award (NU50CK000539-01-05) incorporates Federal laws, regulations, policies, and CDC's *General Terms and Conditions for Non-research Grant and Cooperative Agreements* and ascribes these requirements to the recipient of the award.

A recipient is defined as the entity that receives a grant or cooperative agreement and is responsible and accountable for the use of the funds and for the performance of the project or activity. A recipient is typically a non-Federal entity.¹⁰ The award recipient must establish and maintain effective internal control over the Federal award (45 CFR § 75.303). The award recipient is responsible for oversight of the operations of the award activities and must monitor these activities to ensure compliance with applicable Federal requirements (45 CFR § 75.342).

Recipients that subaward funds to other organizations, termed subrecipients, are required to monitor the activities of the subrecipient to ensure that the subaward is used for authorized purposes in compliance with Federal statutes, regulations, and the terms and conditions of the subaward (45 CFR § 75.352).

A recipient's financial management system must be sufficient to allow funds to be traced to establish that such funds have been used according to Federal statutes, regulations, and the terms and conditions of the Federal award. (45 CFR §§ 75.302). For costs to be allowable, they must be adequately documented (45 CFR § 75.403).

Costs must also be allocable to a particular Federal award or other cost objective if the goods or services involved are chargeable or assignable to that award or cost objective in accordance with relative benefits received and incurred specifically for the Federal award (45 CFR § 75.405).

HELUNA HEALTH CHARGED SOME COSTS THAT WERE NOT SUPPORTED

Of the 146 sample items we reviewed, Heluna Health claimed costs for 3 sample items totaling \$3,585,834 that were not adequately documented. As the prime recipient of CDC ELC funds, we requested Heluna Health provide documentation to support our sample items.

For two of the three sample items, Heluna Health did not provide adequate documentation to support some costs for which CDPH claimed reimbursement from Heluna Health. These costs included expenditures for personnel, supplies, and equipment, as well as costs that were identified on the LHJ statements of expenditures.

For the third sample item, Heluna Health did not provide documentation that supported the necessity and reasonableness of certain costs. For example, (1) repairs for rented equipment lacked documentation to support the charges and (2) physical examinations for potential employees who were not specifically identified as working on the COVID-19 award. These errors occurred because Heluna Health did not require CDPH to submit supporting documentation for the costs claimed for reimbursement. Instead, Heluna Health accepted statements of expenditures from CDPH that summarized expenditures by cost category such as personnel, supplies, and payments to LHJs.

¹⁰ A non-Federal entity is defined as a State, local government, or nonprofit organization that carries out a Federal award as a recipient or subrecipient (45 CFR § 75.2).

Additionally, Heluna Health has a *Sub-recipient Monitoring Plan* and a *Sub-recipient Monitoring Guide*. The *Sub-recipient Monitoring Guide* states that Heluna Health is responsible for monitoring the financial activities of its sub-recipients to ensure proper stewardship of funds. Heluna Health stated it conducts annual monitoring of subrecipients and uses the *Sub-recipient Monitoring Plan* and *Sub-recipient Monitoring Guide*. Both of these documents provide monitoring guidance that begins with performing a risk assessment of subrecipients based on the perceived risk of that subrecipient. The State of California Auditor’s Office, in its report issued April 2021, designated management of COVID-19 funds as high-risk and specifically, CDPH’s management of Federal funds. This report was issued after Heluna Health had subawarded funds to CDPH, and therefore Heluna Health could not have used this report in its assessment of CDPH’s perceived risk. Regardless, as the prime recipient of CDC ELC funds, Heluna Health was responsible for all activities under the award and could not provide evidence of its monitoring activities of CDPH. Without proper oversight of CDPH, including documentation review to support Federal expenditures, Heluna Health is at risk of improperly spending Federal funds.

HELUNA HEALTH COULD NOT PROVIDE ADEQUATE DOCUMENTATION FOR START-UP COSTS

For four sample items, Heluna Health disbursed \$366,850,858 in advances to CDPH for LHJs “start-up costs.” The advances were to support a range of COVID-19 testing and epidemiologic surveillance-related activities as outlined in each work plan contract with CDPH. The advance amount for each LHJ was 25 percent of the LHJ’s budgeted expenditures.

Federal regulations require recipients’ expenditures to be supported by adequate source documentation. Heluna Health’s workplan budget that it prepared for CDC related to this award, indicated that these 25 percent advances would occur between CDPH and LHJs, and CDC approved this workplan.

In support of these four sample items (advances), Heluna Health provided invoices that CDPH submitted for reimbursement that listed a lump sum amount CDPH disbursed to LHJs equaling 25 percent of each LHJ’s total budgeted expenditures. While advances are allowable according to Federal regulation, Heluna Health stated it had no documentation to prove these advances were used for this COVID-19 award.¹¹ Heluna Health stated that these advances were simply 25 percent of the total amount that CDPH would provide to each LHJ. CDPH notified each LHJ of this advance amount in its contractual agreement.

As a result, we were unable to determine whether these advances were reasonable, or whether these funds were used specifically for start-up costs related to the COVID-19 award. Accordingly, we set aside \$366,850,858 related to these four sample items.

¹¹ 45 CFR § 75.305

RECOMMENDATIONS

We recommend that Heluna Health:

- refund \$3,585,834 to the Federal government;
- develop and implement a policy that requires CDPH to provide adequate supporting documentation to ensure the costs claimed are allowable and allocable; and
- work with CDC to determine the allowable portion of \$366,850,858 related to LHJ start-up costs and refund to the Federal Government any unallowable amount.

HELUNA HEALTH COMMENTS

In written comments to our draft report, Heluna Health did not concur with our recommendations. Instead, Heluna Health described the actions it has taken or is planning to take to address our three recommendations.

Regarding our first recommendation, Heluna Health stated it provided substantial supporting documentation during the audit for the sample items selected and that the draft report did not identify which costs were at issue. However, Heluna Health stated it would provide supporting documentation to CDC and work with CDC “to explain to CDC's satisfaction the allowability of the costs” that we had determined to be unallowable.

Regarding our second recommendation, Heluna Health stated that it provided appropriate substantiating data for costs incurred but recognizes the importance of strong policies and, as a supplement to its existing policies, will develop and implement a documentation policy to address allowability and allocability of costs. That policy will (1) specify which particular documents must be provided in support of costs and (2) add requirements for increased documentation for larger categories of cost or funding that pose a higher degree of risk, including the addition of requirements that address concerns that arise during performance.

Regarding our third recommendation, Heluna Health stated that the agreement with CDPH allowed for advance payments during the audit. Heluna Health provided the OIG with extensive documentation, which included approximately 400 pages of documents, supporting the expenditures of the advance payments by the LHJs. In addition, Heluna Health stated the draft report does not identify specific costs covered by the advances that are not allocable to the project or unreasonable in amount. Heluna Health stated it would work with CDC to explain the costs covered by the advances to the LHJs. Heluna Health also stated it would ensure CDC understands the costs incurred and the substantiation for such costs.

OIG RESPONSE

Regarding our first recommendation, for the three sample items in error, we analyzed all documentation provided by Heluna Health, including multiple re-submissions of the same documentation. In addition, prior to the issuance of the draft report, we met with Heluna Health multiple times to discuss which portion of costs in each sample item was allowable or unallowable because of inadequate documentation. We gave Heluna Health numerous opportunities to provide support for the specific sample items at issue.

Regarding our second recommendation, we appreciate the actions Heluna Health indicated it will take to address the development and implementation of a policy requiring supporting documentation to ensure that the costs claimed are allowable and allocable.

Regarding our third recommendation, our report indicates adequate documentation to support these advances was not provided, thus we have no assurance that these costs were used specifically to support the ELC COVID-19 award. Specifically, the documentation only listed a lump sum amount equaling 25 percent of each LHJs budgeted expenditures. We requested on multiple occasions documentation to show that these funds were used in the performance of the COVID-19 awards. Even though Heluna Health stated it provided 400 pages of documentation from CDPH (or the LHJs), this documentation did not support the expenditures incurred with these funds. As stated in its response to our draft report, Heluna Health relied on the attestation by CDPH that these funds “were used for the COVID award.” Finally, in a meeting with Heluna Health personnel on February 13, 2024, when asked again whether Heluna Health had documentation to support that these advances were used in the performance of the COVID-19 award, Heluna Health personnel stated that because these were advances, there was no support documentation available for review other than the “breakdown and letters” Heluna Health sent each county.

Based on Heluna Health’s comments to our draft report regarding the issuance of the State of California Auditor’s report, we have edited this final report to reflect the timeline.

We maintain that our findings and recommendations are valid.

Heluna Health’s written comments are included as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$587,835,904 in total CDC ELC COVID-19 payments made to Heluna Health. We selected a stratified random sample of 146 line items and reviewed \$561,744,697 in costs.

We did not assess the overall internal control structure of Heluna Health. Instead, we limited our review to Heluna Health's internal controls for ensuring compliance with CDC COVID-19 award requirements.

We conducted our audit from August 2022 to February 2024.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable COVID-19 appropriation bills, Federal requirements, CDC guidance, and Heluna Health policies and procedures;
- reviewed Heluna Health's agreement with the CDPH;
- interviewed CDC officials to obtain an understanding of advances for startup costs pertaining to COVID-19 ELC awards;
- reviewed Notices of Awards, budgets, work plans, and milestone reports;
- reconciled Heluna Health's COVID-19 expenditures, Federal Financial Reports, and drawdowns;
- reviewed Heluna Health expenditures to ensure funds were being used timely;
- reviewed subawards, memorandums of understanding, and work order agreements;
- provided questionnaires to Heluna Health officials pertaining to its policies and procedures;
- interviewed Heluna Health officials;
- selected a stratified random sample of 146 line items totaling \$561,744,697, (see Appendix B);

- determined the allowability for each of the 146 line items by:
 - reviewing and analyzing documentation received;
 - reviewing vendor contracts and agreements;
 - reviewing allocation letters; and
 - verifying expenditures were related to COVID-19 program objectives;
- determined the total value of line items in error; and
- discussed the results of our audit with Heluna Health officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame consisted of 5 Excel spreadsheets that contained 7,713 transaction line items totaling \$587,835,903 that Heluna Health charged to its ELC COVID-19 award funds for the period March 5, 2020, through September 30, 2021.¹²

SAMPLE UNIT

The sample unit was a line item.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample. Because of the nature and potential risk associated with the different types of transactions, we used the expenditure type as the basis for the stratified sample design. Heluna Health's expenditures for the ELC COVID-19 awards were comprised of five types of transactions: salary and fringe benefits, facility and administration costs, other costs, supplies and travel costs, and contractual costs. The specific strata are shown in Table 1.

Table 1: Sample Design Summary

Stratum	Type of Transaction	Number of Line Items	Frame Dollar Value	Sample Size	Value of Sample
1	Salary & Fringe Benefits	6,447	\$14,352,608	25	\$54,594
2	Facilities & Administration	479	\$3,321,244	25	\$155,128
3	Other Costs	445	\$8,043,141	25	\$182,771
4	Supplies & Travel Costs	296	\$856,940	25	\$90,234
5	Contractual Costs	46	561,261,970	46	\$561,261,970
	Total	7,713	\$587,835,903	146	\$561,744,697

SOURCE OF RANDOM NUMBERS

We generated the random numbers using Office of Inspector General, Office of Audit Services, statistical software.

METHOD FOR SELECTING SAMPLE UNITS

We sorted the line items in each stratum as follows:

¹² These line items were not netting transactions and had a value greater than \$500.

- We sorted each stratum first by the transaction number in ascending order and then by burden cost in ascending order.
- We then sequentially numbered each line item in each stratum and considered this number to be our unique identifier.

After generating the random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

The results of our sample item review only contained errors in the certainty stratum, therefore, we did not estimate the total unallowable costs in the sampling frame.

APPENDIX C: HELUNA HEALTH COMMENTS



May 17, 2024

Department of Health and Human Services
Office of the Inspector General
Office of Audit Services
Attention: Lori Pilcher
Regional Inspector General for Audit Services
Region IV
61 Forsyth Street, SW
Suite 3T41
Atlanta, GA 30303

Re: Draft Report No. A-04-22-02037
Heluna Health Response

Dear Ms. Pilcher:

Heluna Health appreciates the opportunity to respond to the United States Department of Health and Human Services (HHS) Office of Inspector General's (OIG's) draft report number A-04-22-02037 *Heluna Health May Not Have Used California's CDC COVID-19 Funds in Accordance with Award Requirements* (Draft Report).

For the reasons below, Heluna Health respectfully does not concur with the recommendations in the Draft Report but commits to undertake the actions identified in this response.

Heluna Health has made significant investments in its subgrant administration compliance approach. We are committed to the quality of data obtained and submitted in support of funds expended. We are further committed to refinement and enhancement of our practices in response to the topics addressed in the Draft Report. We therefore request that the OIG reconsider its recommendations before finalizing its report. We welcome the opportunity to discuss OIG's findings and recommendations if it would be helpful to the OIG, as well as to work with the Centers for Disease Control and Prevention (CDC) to explain to the agency's satisfaction why the questioned costs are allowable.

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I. Background

Heluna Health has served as the bona fide agent for the California Department of Public Health (CDPH) for purposes of receipt and disbursement of federal funding for more than 20 years. In numerous audits over the last decade, Heluna has not been found to have any material deficiencies or significant adverse findings.

The COVID-19 pandemic was a uniquely challenging time for the nation, including local health jurisdictions and many other organizations and individuals. The Draft Report notes that “COVID-19 has created extraordinary challenges for the delivery of health care and human services to Americans.” *Id.* at 1.

The Draft Report concerns two Epidemiology and Laboratory Capacity (ELC) cooperative agreements (awards) for COVID-19 funding received and administered by Heluna Health for CDPH. The awards were for Enhancing Detection and an Enhancing Detection Expansion. The purpose of the Enhancing Detection program in 2020 was to build on, leverage, and expand COVID-19 response activities and advance the State’s work to close racial and ethnic disparities related to COVID-19. The Enhancing Detection Expansion program in 2021 provided additional funding to respond to the challenges posed by COVID-19.

The California Department of Public Health (CDPH) designated Heluna Health as its bona fide agent to manage its ELC COVID-19 funding. Heluna Health sub-awarded ELC COVID-19 funds to CDPH, which contracted with more than 60 local health jurisdictions (LHJs) to assist with local COVID-19 response efforts.

The Draft Report reflects that the audit period examined by the OIG was March 2020 through September 2021. Draft Report at 5. The Draft Report sets forth three recommendations. Specifically, the Report recommends that Heluna Health:

- refund \$3,585,834 to the Federal government;
- develop and implement a policy that requires CDPH to provide adequate supporting documentation to ensure costs claimed are allowable and allocable; and
- work with CDC to determine the allowable portion of \$366,850,858 related to LHJ startup costs and refund to the Federal Government any unallowable amount.

Id. at 7.

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II. Discussion of Findings and Recommendations in the Draft Report

We address below the three findings and recommendations in the Draft Report.

A. Specific Costs Identified As Unallowable

The Draft Report states that Heluna Health “claimed costs for 3 sample items totaling \$3,585,834 that were not adequately documented.” Draft Report at 5. These costs are separated into two categories, as discussed below.

1. Documentation of Costs

The Draft Report states:

For two of the three sample items, Heluna Health did not provide adequate documentation to support some costs for which CDPH claimed reimbursement from Heluna Health. These costs included expenditures for personnel, supplies, and equipment, as well as costs which were identified on the LHJ statements of expenditures.

Id. at 5. In referring to “some costs,” the Draft Report does not identify which costs were at issue, the relevant LHJ(s), or the amount at issue for each category of cost. The use of the term “some” suggests that some portion of these costs may have been viewed as adequately documented. In addition, the reference to categories of costs “included” leaves unclear which specific costs were questioned.

In support of its monthly invoices to Heluna Health, CDPH typically included hundreds and up to 3,000 pages (each) of supporting detail, such as timesheets, vendor invoices, and other documentation.

Heluna Health provided substantial supporting documentation during the audit for the OIG’s review. Heluna Health provided several hundred thousand pages of documentation applicable to the audit period, including invoices, accounting transactions, and subrecipient agreements, etc., for the OIG to make 146 audit sample selections. The documents Heluna Health provided were in response to specific requests from the OIG and uploaded to the OIG’s Kiteworks secured website. For the 146 audit samples selected by the OIG, the total amount of data uploaded included approximately 2,000 files using more than 9 Gigabytes in cumulative

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data storage and totaling an estimated 28,000 pages. This ample documentation supported the costs claimed in the invoices.

2. Necessity and Reasonableness

The Draft Report states:

Heluna Health did not provide documentation that supported the necessity and reasonableness of certain costs. For example, (1) repairs for rented equipment lacked documentation to support the charges and (2) physical examinations for potential employees who were not specifically identified as working on the COVID-19 award.

Id. at 5. The Draft Report further states:

These errors occurred because Heluna Health did not require CDPH to submit supporting documentation for costs claimed for reimbursement. Instead, Heluna Health accepted statements of expenditures from CDPH that summarized expenditures by cost category such as personnel, supplies, and payments to LHJs.

Id. The Draft Report thus suggests that Heluna Health accepted a bare explanation that funds were expended (“statements of expenditures”) in generic categories (“personnel, supplies. . .”) without any substantiation from the LHJs. That is incorrect. As noted above, CDPH invoices to Heluna Health were supported by thousands of pages of timesheets, vendor invoices, and other materials. These supporting materials were not individually annotated to address necessity, but CDPH attested to them as incurred in support of activities set forth in the relevant work plan. Responses to COVID-19 required the use of equipment, and equipment occasionally must be repaired to work properly. For example, a new COVID-19 laboratory (covered by the workplan) required a large piece of very heavy equipment that necessitated an extensive upgrade to the flooring to accommodate this testing equipment. The repair costs were necessary and appropriate. Physical examinations are necessary for personnel working in a public health capacity to respond to a pandemic. Accordingly, the costs were necessary, allowable and appropriate for the effort covered by the work plans.

With regard to reasonableness, the Draft Report does not identify which consideration(s) set forth in 45 C.F.R. 75.404 underlie its findings regarding reasonableness. The regulations recognize that a “cost is reasonable if, in its nature and amount, it does not exceed

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that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost.” *Id.*

Plan of Action: Although Heluna Health does not concur in the finding or recommendation, Heluna Health will provide supporting documentation to CDC and work with CDC to explain to CDC’s satisfaction the allowability of the costs.

B. Documentation

During the audit, the OIG inquired of Heluna Health as to its policies and practices with regard to internal controls. Heluna Health provided the requested information and explained the effectiveness of its internal controls.

The Draft Report states that the “State of California Auditor’s Office designated management of COVID-19 funds as high-risk and specifically, CDPH’s management of Federal funds.” Draft Report at 5.¹ The Draft Report further states that Heluna Health “did not identify CDPH as a high risk subrecipient and could not provide evidence of its monitoring activities of CDPH.” *Id.* The cited audit report is dated April 2021 and thus could not have been considered by Heluna before the relevant subawards were made to CDPH (August 8, 2020 and March 2, 2021). Heluna Health will take the State of California’s findings into account in its risk assessment and administration of funding involving CDPH.

Heluna Health’s agreement number 0187.0150 with CDPH provides that “on a monthly basis, the State will provide Heluna Health with an invoice that will include documentation of the advanced funds being disbursed to the LHJs along with proof of payment which includes transmittal date.” Article 4 (Payments), subpara. (g). The agreement further provides that on a “monthly basis, the State will submit actual expenditures by LHJ with their monthly invoice to track and offset the advance start-up costs.” *Id.* This agreement covered the majority (nearly \$297 million) of the total advance funds (\$366 million) discussed in the Draft Report. Heluna Health agreement number 0187.0270 covered the remainder. The latter agreement also required CDPH to include documentation of the advanced funds being disbursed to the LHJs along with proof of payment which includes transmittal date. Article 4 (Payments), subpara. (g).

Heluna Health received substantial documentation from CDPH showing expenditures from the funds advanced. During the audit, Heluna Health was able to provide substantiation and supporting data for all costs incurred. Heluna Health obtained such information from CDPH

¹ The cited report is California State Auditor Report 2020-612, *California Department of Public Health: It Could Do More to Ensure Federal Funds for Expanding the State’s COVID-19 Testing and Contact Tracing Programs Are Used Effectively*, April 2021.



and the relevant LHJs. The data provided to the OIG during the audit included approximately 400 pages of documents regarding the advance payments.

Plan of Action: Although Heluna Health believes it provided appropriate substantiating data for costs incurred, Heluna Health recognizes the importance of strong policies to support disbursement of funds and reimbursement of costs under cooperative agreements and grants. As a supplement to its existing policies, Heluna Health will develop and implement a documentation policy to address allowability and allocability of costs, including measures to (i) specify particular documentation that must be provided in support of costs and (ii) allow for increased documentation requirements for larger categories of cost or funding that poses a higher degree of risk, including addition of requirements during the course of administration to address concerns that arise during performance.

As noted above, Heluna Health also will consider the State of California’s findings in its risk assessment and administration of funding involving CDPH.

C. Advance Payments

For its efforts under the Enhancing Detection and Enhancing Detection Expansion agreements, Heluna Health prepared workplans that were submitted to, and approved by, CDC. Heluna Health administered the cooperative agreements in accordance with the relevant workplans.

As the Draft Report notes, Heluna Health “disbursed \$366,850,858 in advances to CDPH for LHJs ‘start-up costs.’” *Id.* at 6. These “advances were to support a range of COVID-19 testing and epidemiologic surveillance-related activities as outlined in each work plan contract with CDPH” and were “25 percent of the LHJs budgeted expenditures.” *Id.*

Article 4(b) of the agreements between Heluna Health and CDPH allowed for advance payments. The ED Expansion workplan explained that “LHJs will receive a 25% advance payment for start-up costs, and then get reimbursed for actual expenditures once the 25% advance has been fully expended.” ED Expansion Workplan (March 18, 2021) at 2. The Draft Report recognizes that Heluna Health’s “workplan budget that it prepared for CDC” for this award “indicated that these 25 percent advances would occur between CDPH and LHJs” Draft Report at 5. The Report further states that “CDC approved this workplan.” *Id.* The Report notes that advance payments are permitted under the regulations. *See id.* at 6, n11 (citing 45 C.F.R.75.305).

The Cooperative Agreement Guidance for the Enhancing Detection and Enhancing Detection Expansion programs neither prohibits the use of advances nor expressly addresses them. Although dated after the Enhancing Detection agreement was awarded, the Office of

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Management and Budget (OMB) recognized the value of covering pre-award costs. OMB guidance for COVID states:

Pre-award costs: Awarding agencies may allow necessary pre-award costs that are incurred: (i) from March 15, 2021, through the Public Health Emergency Period; and (ii) prior to the effective date of a Federal award. (2 CFR § 200.210, 2 CFR § 200.458).

OMB Memorandum M-21-20 (March 19, 2021) at 10.

The advance payments enabled LHJs to fund ongoing COVID response activities, including hiring personnel, procuring critical supplies and equipment, and other activities outlined in the workplans, without incurring additional debt. Following the advances, the balance of the allocated Enhancing Detection and Enhancing Detection Expansion funding was only accessed through invoicing and documentation of expenses in arrears.

The Draft Report asserts that Heluna Health “stated it had no documentation to prove these advances were used for this COVID-19 award.” *Id.* at 6. The CDPH invoices against the advances, however, attested that the claimed expenditures were used for the COVID award.

During the audit, Heluna Health provided the OIG with extensive documentation supporting the expenditures of the advance payments by the LHJs. As previously stated, this support included approximately 400 pages of documents regarding the advance payments. The Draft Report does not identify specific costs covered by the advances that are not allocable to the project or unreasonable in amount.

Plan of Action: Heluna Health will work with CDC to explain the costs covered by the advances to the LHJs. Heluna Health will ensure CDC understands the costs incurred and the substantiation for such costs.

Regarding the title of the Draft Report, we respectfully request that it be changed to, “Recommendations to ensure use of California’s CDC COVID-19 fund align with award requirements.”

III. Conclusion

For the reasons set forth above, Heluna Health does not concur with the recommendations in the Draft Report but will undertake the actions recommended therein in terms of enhancing its documentation policies and practices and working with CDC to explain the allowability of the costs covered by the advance payments.

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Please contact the undersigned if you have any questions or require additional information. Again, Heluna Health appreciates the opportunity to respond to the Draft Report and looks forward to working with the CDC to resolve any remaining questions.

Respectfully submitted,

A handwritten signature in black ink that reads "Brian Gieseler". The signature is fluid and cursive.

Brian Gieseler, CFO

Cc: Dr. Blayne Cutler, President, and CEO

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