

<p><b>ACF</b> Administration for Children and Families</p> <p><b>CMS</b> Centers for Medicare and Medicaid Services</p>	<p><b>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> <b>Administration for Children and Families</b></p>	
	<p><b>1. ACF Log No:</b> ACF-OA-PI-13-01</p>	<p><b>2. Issuance Date:</b> June 11, 2013</p>
	<p><b>3. Originating Office:</b> Administration for Children and Families/Office for Administration</p>	
	<p><b>4. Key Words:</b> Advance Planning Document (APD); APD Reform; Federal Financial Participation (FFP); Commercial Off-the-Shelf (COTS) Software; APD Waivers</p>	

**PROGRAM INSTRUCTION**

**TO:** State Public Assistance Agencies; Tribes, Tribal Organizations and Consortia (Tribes) with Federally Approved Public Assistance Programs; State and Tribal Information Technology Leadership; and Other Interested Parties

**SUBJECT:** Waiver Process for the Use of Federal Funding for Commercial Off-the-Shelf (COTS) Software Products

**LEGAL AND RELATED REFERENCES:** 45 CFR Part 95; 45 CFR Part 92; OMB Circular A-87; 75 FR 66319 (October 28, 2010). This supersedes ACYF-CB-PI-11-08.

**PURPOSE:** This Program Instruction (PI) provides information to states and tribes (agencies) who request federal financial participation (FFP) for costs associated with an automated data processing project covering one or more of the following human service programs established by the Social Security Act: title IV-E and title IV-B (Child Welfare), title IV-D (Child Support), and title XIX (Medicaid). The Child Welfare, Child Support, and Medicaid programs are covered by the Department of Health and Human Services’ (DHHS) Advance Planning Document (APD) rules at 45 CFR 95, Subpart F.

The PI addresses the use of commercial off-the-shelf (COTS) software applications by these agencies, including purchased, leased and hosted proprietary software products and software-as-a-service (SaaS) applications. This issuance offers guidance regarding the information that must be provided by an agency in an APD when requesting a waiver of rules limiting the use of FFP for COTS products, including those designed for any of the covered programs. For initiatives that fall below the APD thresholds requiring the submission of a Planning, Implementation or related APD Update as defined at 45 CFR 95, Subpart F, the APD may take the form of a letter providing the information listed in this guidance.

The Department of Health and Human Service (DHHS) consulted with the Food and Nutrition Service’s (FNS) State Systems Office to develop this guidance. While this guidance only applies to the Department of Health and Human Service programs identified above, FNS is supportive of the outcomes that this process will achieve. For enterprise software projects that also include

components funded by the Department of Agriculture, agencies should consult with FNS to determine if a waiver is needed.

This guidance is effective as of the issuance date of this PI and does not affect any APD waiver previously approved by a DHHS program office covered by the regulations at 45 CFR 95 Subpart F.

## **BACKGROUND:**

Given the cost of developing, implementing, and maintaining automated systems, DHHS is providing this guidance so that agencies may take advantage of the full array of new and evolving technology products and services that can support the efficient operation and administration of the Child Welfare, Child Support, and Medicaid programs (human service programs). This guidance is specifically focused on COTS software products designed for human service programs and provided as either licensed or hosted services. Currently, these types of software products are restricted under DHHS APD rules.

Under 45 CFR 95.617, agencies are unable to claim FFP for proprietary COTS products or services designed to support the covered human service programs. This has limited the technology options available for automated data processing projects. As part of the Department's continuing commitment to promote flexibility for states and tribes operating human service programs, we are providing this guidance on the use of a waiver authorized at 45 CFR 95.627, which may address these prohibitions. The flexibility provided through this PI also reflects insights gained during discussions with tribes under DHHS's Tribal Consultation process related to child welfare automation.

We additionally describe a process whereby agencies whose overall project costs are under the thresholds defined at 45 CFR 95 Subpart F, and are thus not subject to APD submission requirements, may seek a waiver of these COTS rules. For example, an under-threshold project might include the extension of an existing tribal COTS system to track child welfare cases, or the acquisition of a COTS module to replace a financial data-exchange process in an operational system.

This PI on the use of COTS products developed for human service programs applies to software applications installed and operated on agency-owned infrastructure or accessed via the internet as a service by the agency's staff. COTS software is defined in the DHHS APD rules at 45 CFR 95.605 as those proprietary software products that are ready-made and available for sale to the general public at established catalog or market prices. Approval of a waiver to use this type of software must be requested through an APD. If the total project costs fall under the financial thresholds requiring an APD, the waiver request may be submitted to the appropriate federal agency as an APD in letter format, providing the information listed in this guidance. For cross-agency projects funded by DHHS and incorporating more than one of the Medicaid, Child Support and Child Welfare programs, agencies should use established multi-operational division processes.

Through this PI, DHHS is providing guidance on how agencies may request a waiver to use proprietary COTS or hosted applications. The proposed approach must conform to all federal regulations, including those related to open procurements and data ownership, and must be capable of demonstrating its effectiveness and economy in supporting agency administration.

## **DISCUSSION:**

The DHHS APD regulations at 45 CFR 95.627 allow an agency to apply for a waiver by presenting an alternative approach to the applicable regulatory provisions. A waiver of the provisions of 45 CFR 95.617 that prohibit FFP for proprietary software applications developed for public assistance programs, or not available to the general public at a standard catalog price, would allow an agency to use federal funds for this type of COTS product or service. This waiver would apply whether the owner of the COTS product or another vendor implements or operates the solution or service.

In general, the agency must demonstrate in its waiver request that the use of a COTS product or service will provide a more economical, efficient and effective approach to service delivery and program administration than the use of a custom-built or transferred information technology (IT) solution. When submitting a waiver request related to the use of COTS products or services, DHHS expects agencies to address the requirements defined at 45 CFR 95.627 as well as issues that are unique to the proprietary services environment. This would include issues typically defined in a service level agreement, such as data access, security and ownership, and plans addressing data conversion, transition, and business continuity.

The federal review of the waiver request will focus on the defined waiver requirements and the applicant agency's inclusion of contractual protections and safeguards that clearly demonstrate that the agency maintains complete administrative control and ownership of its data stored in a proprietary application. The waiver application must state how the agency will retain reliable access to the application, and define standards for operational uptime and data security through its contracts or service agreements. We also expect assurance that the proposed COTS solution will provide non-proprietary data formats or transformations, so the agency's data may be reliably and easily extracted in industry standard formats during the course of and upon the end of the contract or service agreement period.

The agency's waiver request should address information integrity and the provisions to safeguard the security and confidentiality of data. This includes written policies for access to data by agency and vendor personnel, and specifications for those individuals allowed access to data for purposes of data review, extraction, conversion, or other data manipulation, and a means to determine the personnel who accessed such data. Agency contracts or service agreements must clearly specify penalties for data misuse, unauthorized access or data tampering, and describe protocols for the vendor to notify the agency in the event of security breaches or other unauthorized access to agency data.

Proprietary products, in comparable uses, must be available at a similar pricing structure to all customers. Agency purchasing or licensing agreements must represent responsible fiduciary practices and reasonable best efforts to secure competitive pricing. The applicant agency must

conduct its procurement to secure software or services as described in 45 CFR 92. The federal agencies responsible for reviewing APDs believe that conducting state and tribal procurements in a full and open competitive manner will minimize risks and lower costs of software acquisitions. This belief is reflected in 45 CFR 95.613, where the federal agencies retain the authority to provide greater oversight if it is determined the procurement process is an impediment to competition that could impact project costs or increase the risk of failure.

The APD requesting federal approval of a waiver to implement an otherwise ineligible COTS solution must remain compliant with all other relevant DHHS APD provisions, including the following:

- Applicants should outline their procurement approach for promoting free and open competition in the procurement of a COTS product. The APD must describe the approach that the agency will use in the request for proposals (RFP) to allow and encourage multiple vendors to consider submitting a proposal.
- The request must specify procedures the agency will take to secure and protect federal access rights to system documentation, and cost and operational records. As defined at 45 CFR 95.615, DHHS will maintain its right of access to systems and records when FFP has been provided. The right of access may include such material as user documentation, run-books, operational manuals, return-to-service procedures, release management procedures, vendor service agreements and data retention policies. DHHS must be able to access any operational and cost records that are necessary for the determination that conditions of the waiver approval are being met, to verify program requirements are being satisfied, and determine if the system solution is efficient, effective and economical.
- DHHS rules regarding submission of claims or allocation of costs when seeking FFP for an automated data processing project remain unchanged. Any discounts, rebates or commissions offered to the state or tribe prior to or after the solicitation process must be considered in determining total federal costs. Policies and procedures for claiming costs for federal funding are discussed at 45 CFR 95.631.

#### **INSTRUCTION:**

A waiver request to use a proprietary product or service developed to support one or more public assistance programs must include:

- A detailed summary of the alternatives analysis and feasibility study (45 CFR 95.610) undertaken by that agency to justify the use of a COTS solution, which addresses business, technical, and financial analysis, and a cost-benefit study including a discussion of implementation and operational costs and expected costs for the proposed solution;
- An explanation of how the requirements of 45 CFR 95.617 that the agency seeks to waive are unnecessary or limit the agency's ability to meet program requirements, or how the waiver would deliver benefits in the areas of efficient, effective and economical program administration (45 CFR 95.627(c));
- A detailed plan addressing how the agency will transition from the use of a COTS application, proprietary system or service to another application or solution, should the agency no longer use the COTS product or service;

- A description of how the agency will secure and protect federal access rights to system documentation, and operational and cost records as defined at 45 CFR 95.615;
- A discussion of how the agency using the COTS product or service will comply with data sharing and data interoperability goals of the applicable federal agencies involved in the project;
- A plan detailing how the agency will encourage competition in its procurement of a COTS product (45 CFR 95.613) or proprietary application or service; and
- A description of the risk mitigation plan associated with the use of proprietary products that addresses:
  - the agency’s ability to meet its needs for application enhancement or modifications within a vendor-defined release schedule;
  - policies and procedures for data security and protection of client confidentiality;
  - continuity of data access and data recovery;
  - the penalties for data misuse, unauthorized access, or security breaches; and
  - provider termination, data retention and data disposition policies.

The waiver request may be included in an APD, an APD update, or for projects under threshold, an APD in letter format that addresses the requirements listed in this guidance.

**REVIEW AND APPROVAL PROCESS:**

Approval of the waiver request may be granted if the agency demonstrates that the alternative approach will safeguard the interests of the state or tribe and the federal government, and will enable the agency to be in substantial compliance with the remaining conditions for FFP.

If approved, the waiver will become part of the agency’s approved APD. Disapproval of the waiver request will result in disapproval of the entire APD; this disapproval is not subject to an administrative appeal. Please note that if a waiver request is not approved, the agency does not forfeit FFP entirely, but can submit a new APD for the project.

All waiver requests will be treated as controlled correspondence, with a response within 60 days of receipt and acknowledgement by the federal government.

**INQUIRIES:** Director, Division of State Systems, CB/ACYF/ACF/DHHS  
 Director, Division of State Systems, Center for Medicaid and State Operations  
 Director, Division of State and Tribal Systems, OCSE/ACF/DHHS

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**Questions and Answers related to ACF-OA-PI-13-01, Waiver Process for the Use of Federal Funding for Commercial Off-the-Shelf (COTS) Software Products**

1. *In Part 11, Section 11276.3, of the CMS State Medicaid Manual, CMS funding is authorized for the license costs of certain proprietary software. Does this Program Instruction change that provision?*

No, CMS, OCSE and CB currently fund the cost to license certain proprietary software allowed by 45 CFR 95.617, and this Program Instruction does not change the ability of a state or tribe to claim those costs.

2. *May we use proprietary software approved by one DHHS operational division in a different project?*

There is no prohibition against a state or tribe requesting a waiver for software prohibited by 45 CFR 95.617. Furthermore, if the COTS software is allowed under 45 CFR 95.617, it may be used by any of the DHHS programs following the Advance Planning Document rules at 45 CFR Part 95 Subpart F. Note that FFP rates may differ, and the Office of Management and Budget's Circular A-87 cost allocation principles may apply to the different benefitting programs.

3. *My total project costs are unknown. For Phase 1, costs are under threshold, but the total project costs may eventually exceed threshold limits. May I submit a waiver request in a letter format?*

Yes. However, states or tribes should be able to estimate the total cost of their projects.

4. *What should be in a waiver letter?*

As noted in the Program Instruction, the letter should include the information listed in this guidance, including the findings of an alternatives analysis and an explanation of how the waiver will assist the agency in meeting program requirements. Plans for transition from the COTS product if it is no longer available to the agency, and to encourage competition in its procurement should also be summarized. Plans to mitigate risks associated with the use of propriety products must also be included.

For cross-agency projects funded by DHHS and incorporating more than one of the Medicaid, Child Support and Child Welfare programs, agencies should submit waiver requests to the applicable program offices and the use established multi-operational division processes.

5. *Will FNS support the use of proprietary software prohibited by their APD rules?*

The Food and Nutrition Service's State Systems Office participated in the development of this guidance and is supportive of waiver requests for otherwise prohibited COTS software. However, due to differences in regulatory language, waivers may not be necessary in some situations involving FNS programs. As you consider system options, check with FNS to determine the applicability of FNS waiver requirements.

6. *My agency has a waiver for a proprietary software product granted under the provisions of the Program Instruction ACYF-CB-PI-11-08, granted prior to the effective date of this new PI. Must we re-apply for waiver approval for that product under the provisions of this PI?*

No.