



**State of Washington
Health Care Authority**

**Planning/Implementation Advance Planning Document (P/I APD)
for Prescription Drug Monitoring Program (PDMP)**

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FINAL

For questions, please contact:
Cathie Ott, Division Director
ProviderOne Operations & Services
Washington State Health Care Authority
PO Box 45514
Olympia, Washington 98504-5514
(360) 725-2116
E-mail: cathie.ott@hca.wa.gov

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1. Statement of Need and Objectives

1.1 Purpose & Vision

The state of Washington has been working to address the opioid epidemic for several years and has increased activity to meet the complex challenges this epidemic presents. In October 2016, Governor Inslee issued an [executive order](#) to help bring attention and focus to addressing the epidemic. The order calls on many state agencies and partner organizations to work together to carry out the [Opioid Interagency Working Plan](#).

The Prescription Drug Monitoring Program (PDMP) is an important component of the working plan. The PDMP allows providers with prescriptive authority the ability to check a patient's prescription history. Checking the PDMP can alert providers of patient opioid or other controlled substance use, which may lead to more informed treatment decisions and fewer opioid deaths.

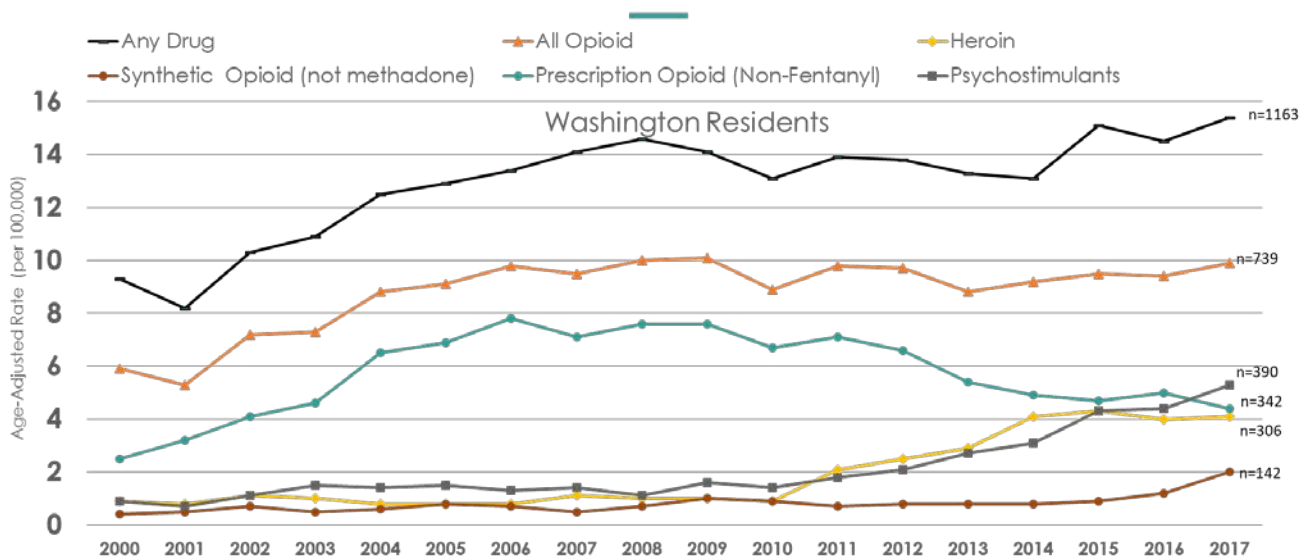
The State's current PDMP system was implemented in 2011. Washington State is the only state in the United States that remains on this legacy product. The Washington State Department of Health (DOH) intends to conduct a competitive procurement to replace the legacy PDMP system.

The Washington State Health Care Authority, in collaboration with DOH, is submitting this P/I APD to request funding to implement a PDMP system with enhanced functionality that will provide a robust treatment decision making tool for healthcare providers. This is essential for addressing the epidemic because by making better informed treatment decisions providers can help prevent opioid misuse, abuse and overdose.

1.2 Background

Drug overdose (mostly caused by opioids) kills more people in Washington State than traffic accidents. Washington State had nearly 700 opioid-related overdose deaths in 2016. The rise in opioid-related overdose deaths is a public health emergency and epidemic.

Overdose Death Rate by Drug Type (2000-2017)



2017 data finalized
Data run: 19Nov2018

Washington State Department of Health | #

Source: DOH death certificates

Use of the PDMP will increase substantially with the enactment of new rules requiring Washington-licensed opioid prescribers to register for and use the program when prescribing opioids. The department expects over 30,000 additional prescribers and their delegates (e.g., registered nurses and medical assistants) to start using the PDMP.

H.R. 6 - SUPPORT for Patients and Communities Act became law on October 24, 2018. It includes several provisions related to Prescription Drug Monitoring Programs (PDMPs), including Section 5042 that creates a Medicaid requirement for a “qualified PDMP” and makes funding available for a time limited basis (October 1, 2018 to September 30, 2020) at 100 percent Federal Medical Assistance Percentage (FMAP) for expenditures for a qualified PDMP.

Law provisions require Medicaid providers to check relevant prescription drug monitoring programs (PDMPs) before prescribing a Schedule II controlled substance. The policy also encourages Medicaid providers to integrate PDMP usage into a Medicaid provider’s clinical workflow and establishes standard criteria that a PDMP must meet to be counted as a qualified PDMP. Finally, section 5042 requires state Medicaid programs to report to CMS on PDMP data and information.

In addition, CMS approved a Medicaid Institutions for Mental Diseases (IMD) Waiver amendment to the State’s Medicaid Transformation Program. The IMD Waiver includes requirements for a Substance Use Disorder (SUD) Health IT Plan. Tasks in the SUD Health IT Plan are an unfunded mandate. The SUD Health IT Plan includes requirements related to PDMPs, many of which mirror requirements for a “qualified PDMP” established in Section 5042 of the Support Act. The activities of this P/I APD will support some of the tasks required in the IMD Waiver SUD Health IT Plan.

1.3 Statement of Need

Washington State's current PDMP was implemented in 2011. The marketplace has since advanced in improved and new functionality that can greatly further efforts to address the opioid epidemic in Washington. The Department of Health seeks to implement a solution that will:

- streamline the provider's registration and login for those having to access the PDMP. This is critical to ensure they can quickly access this critical information during the short time they have for a patient appointment.
- more quickly process data files submitted to ensure providers have as up-to-date information as possible. The current legacy system takes up to 72 hours to process a file submitted. That delay is too long in emergency and urgent care settings, when providers do not have an on-going relationship with the patient and may not see the patient again. Given how quickly someone can fill a prescription, it is essential to ensure the data is up to date as possible for the best informed treatment decisions.
- promote the ability to analyze and visualize public health data to inform policy decisions to address the opioid epidemic. The ability to understand the epidemic, track it, and respond relies on a strong ability to analyze the data at the state and local level.
- allow staff to more effectively track and monitor dispenser data reporting to ensure data are accurate and complete. The current legacy system does not adequately automate dispenser reporting compliance checks which requires a lot of manual work by staff and also does not easily allow the tracking of missing data or data that requires corrections.
- ensure program staff can easily track important data on registrations, utilization, and other key dashboard metrics. The current legacy system does not have a robust administrative reporting tool.
- ensure the health information exchange connection is maintained for integrated access via electronic health record systems. This is essential to streamlining provider access within clinical workflow and ensuring the data gets used more regularly.

DOH conducted a lean project aimed at improving the PDMP's ease of use for providers. The goal was to find ways to make the system easy for providers to register for and use while continuing to meet security/privacy requirements for protected health information. The project had a charter and a stakeholder workgroup. The results of this project has helped inform the design of a new system that will improve end user efficiency.

Washington State is in need of a PDMP solution that will meet the key needs noted above that are critical to effectively address the opioid epidemic. This Planning/Implementation APD requests federal funds to procure and implement a PDMP solution.

The scope of this request also includes technical assistance consulting services to assist providers with integrating PDMP data into the workflow of their electronic health record systems, and three potential HCA investments in interoperable health information technology that will support Washington State efforts to combat the opioid crisis through integrating the PDMP and CDR utilizing:

- electronic consent management,

- the availability of additional clinical data sources, and
- reporting for clinical and case management.

As part of a multi-pronged approach to addressing the opioid crisis, HCA sees a continual need to assess the current and future interoperable health information technology capabilities needed for providers that serve persons with behavioral health conditions. This work supports Promoting Interoperability Program goals and metrics while integrating with HCA's major initiatives of supporting transformation of the Medicaid delivery system, enabling physical health and behavioral health integration, and integrating with the PDMP for addressing the opioid crisis.

Centralized consent management is needed to address the barriers that exist for sharing health information related to clients who receive substance use disorder treatment or are part of the growing opioid use disorder epidemic. HCA intends to continue researching an electronic consent management solution that allows patient-authorized exchange of sensitive data and integrates between statewide systems such as the PDMP, the Health Information Exchange (HIE), and the Washington HealthPlanFinder, the state's health benefit exchange. HCA will work in partnership with behavioral health providers and community advocates to develop a system that ensures safe, secure, and effective management of patient consent, and removes provider burden associated with collecting and sharing information with clinical information systems such as the PDMP. HCA seeks a solution that is scalable, sustainable, meets provider needs, and supports Medicaid Transformation.

There is growing evidence that addressing all aspects of a patient's health and social needs lead to better health outcomes and lowered expenditure by health agencies. HCA wants to integrate PDMP information with other disparate information sources to support full physical, behavioral, and social recovery from an opioid use disorder. However, the burden of accessing separate and disparate information systems drives significant physician burn out and drives up administrative expenses at practices, clinics, hospitals, and other care providers. HCA seeks to leverage the state health information exchange and clinical data repository as centralized tools which can be used to connect to or aggregate information from these separate systems to promote a "one stop shop" for the information clinicians need to promote integrated care and address behavioral health, social need, and opioid use concerns. HCA wants to work with provider groups as mentioned above to ensure that PDMP information, and other information identified by providers as needed to address the opioid crisis, can be made accessible in a way that reduces provider burden and allows for dynamic approaches to supporting patients and communities.

HCA also needs to better understand how the PDMP and other new data sources could be usefully integrated into the workflow for eligible physicians and clinicians at eligible hospitals to help combat the opioid epidemic. HCA is requesting funding to evaluate how to develop customized, use-case driven reports which produce the right information to support clinical decision-making at the point of care through standard and interoperable interfaces. This would support providers accessing information in the PDMP and other state systems as needed to combat opioid use disorder. HCA would also work with providers to enhance the maturity of the case management business area that is part of the Medicaid enterprise. During the planning phase HCA will seek input on what tools could be developed which allow the request and ingestion of these reports using certified electronic health record technology, the health information exchange, the PDMP, and other provider systems.

The budget request for the HCA initiatives includes funding to complete the planning activities and estimated costs to implement solutions that align with the results of the planning.

2. Requirements Analysis / Alternative Considerations

The current PDMP vendor has indicated that the legacy product that is currently used by Washington State will not be supported beyond June 2021. The legacy product is also inadequate in comparison to other products available with improved functionality that can further Washington State's efforts to address the opioid epidemic.

Information gathered from other states' PDMPs indicates that there may be other service providers in the market that offer similar or improved systems at competitive prices. Through a survey of other states, the department found that there are four other vendors providing PDMP services and at least four more that may be interested in bidding on this type of service.

DOH reviewed the following options when considering system replacement:

- Developing a system in-house
 - Pros: interoperability and interchanges can be built with reuse in mind, internal experience is held for secure access WA already, and system could be supportable by department staff.
 - Cons: lack of experience with internal staff on hosting, increase in help desk needs, reconfiguration of data exchanges would be required, patient matching functionality would be difficult to build and increase in needs for internal staff for maintenance.
- Conduct a competitive procurement for a new system
 - Pros: leverages the expertise of the commercial market, may result in faster implementation, may displace system maintenance requirements for internal staff, interoperability and interchanges can be built with reuse in mind.
 - Cons: use of a vendor solution may not support the agency policy for shared solutions, furthers dependence on third party vendors, and may require custom programming to meet state policies and standards.
- Acquire code from another state and modify for use in Washington as several states have built their own system in-house.
 - Pros: fast method to acquire and reuse an existing system, could lead to joint operations/partnerships for development which could reduce ongoing maintenance, interoperability and interchanges could be built with reuse in mind.
 - Cons: modification to meet WA state requirements will likely result in more time to implement, dependency on other state's personnel to answer questions regarding their software, complexity of conducting and resolving security vulnerabilities, technology being used may not fit into internal staff's capabilities and knowledge base, require more internal help desk to support system, and could present challenges in interfacing with other systems.
- Seek to upgrade from current legacy system to an enhanced system offered by the same vendor and used by many other state PDMPs.
 - Pros: potentially less disruptive option for current users and external partners; it leverages existing relationships with current vendor, avoids cost and time of conducting

a competitive bidding process and contract negotiation; aligns Washington's system with that of more than 40 other jurisdictions nationally; enhancing the existing system would not require migration of existing PDMP data from the existing vendor to a new one.

- Cons: While an enhancement of the current system may improve the functionality of the PDMP, DOH contracting policies and recommendations do not allow for an indefinite contract extension (i.e. DOH must eventually conduct a competitive bidding process).

Based on feedback from DOH's Health Technology Services of DOH's capacity and capabilities to build a PDMP system in house the option of a vendor hosted solution was chosen. Upon review by DOH Procurement Office, it was decided to release an RFP to stay in alignment with state procurement policies. DOH will ensure the RFP and resulting system meets all requirements of Section 1944 of the Social Security Act, including the following:

- Requirements to ensure a covered provider has access to the controlled substance history of a covered individual for at least the last 12 months along with the name, location and contact information of each covered provider who prescribed to the covered individual during that time period;
- Requirements to allow integration of the PDMP data into the workflow of covered providers (which may include their e-prescribing system); and
- Requirements to ensure interstate data sharing with contiguous states. As noted in section 10 of this APD, DOH has secured letters of support from Oregon and Idaho and also have signed onto the agreement for the same hub that these states currently use.

Cost considerations:

According to a recent report (released 5/24/18) by the Congressional Research Service:

"PDMP expenses involve startup costs, funds needed to operate and maintain the programs, and any monies used to enhance program operation and interoperability. Overall program costs can entail

- hardware such as servers;
- software to run the PDMP database and ensure information security;
- connectivity such that pharmacies and dispensaries can enter data, and prescribers and/or law enforcement officials can request and access data;
- staff to administer the PDMP and provide technical assistance; and
- overhead fees."

3. Cost Benefit Analysis

3.1 Major Benefits

According to a research study done by Altarum, the cost of the opioid epidemic to the country has reached \$1 trillion dollars since 2001 (<https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001>). The costs of the opioid crisis are borne by individuals in the form of lost wages; the private sector in lost productivity and health care costs; and federal, state and local governments in lost tax revenue and additional spending on health care, social services, education, and criminal justice.

The Council of Economic Advisors estimates that in 2015, the economic cost of the opioid crisis was \$504 billion, or 2.8 percent of the Gross Domestic Product that year.

(<https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf>).

According to a [study](#) done by Senator Murray’s office the opioid crisis cost Washington State over nine billion dollars in 2016.

While it is difficult to estimate the precise return on investment, it is clear that use of the PDMP helps address the epidemic, and for every life not lost, money is saved.

3.2 Cost Summary

In light of the cost figures from others states and vendor cost proposals reviewed, DOH used an IT Project estimation tool to evaluate the cost of implementing and operating a PDMP system, as a result of a competitive bid process, in Washington. The DOH Enterprise Architecture team used an estimation technique as a foundation to estimate the cost of replacement. At a high level the breakdown is software sizing, level of effort, hardware, and licensing along with resources.

Total Costs

PDMP activity	Amount
PDMP Implementation	
Consulting – Technical Assistance	
Electronic Consent Management	
Additional Clinical Data Sources	
Reporting for Clinical and Case Management	
Total	\$11,212,798

4. Leadership and Governance

4.1 Steering and Governance Committee

4.1.1 Medicaid Enterprise Steering and Governance

Washington's Medicaid systems and operations are managed in a distributed enterprise across multiple state agencies/organizations. In 2018, the State of Washington Health and Human Services (HHS) Enterprise Coalition was established as a multi-organization collaborative that provides strategic direction, cross-organizational project support and federal funding guidance across Washington's health and human services organizations.

The agencies comprising the enterprise coalition include:

- The Health Care Authority (HCA)
- The Washington Health Benefit Exchange (HBE)
- The Department of Social and Health Services (DSHS)
- The Department of Children, Youth and Families (DCYF)
- The Department of Health (DOH)

The Washington State Office of the CIO (OCIO) and the Washington State Office of Financial Management (OFM) are non-voting members of the enterprise.

The Medicaid Enterprise Governance structure focuses on three areas: 1) cross-agency/organization governance and management; 2) modernization and modular replacement of technology; and 3) improving the client/customer experience.

Goals of the Enterprise Governance structure include:

- Establish a collaborative decision-making and management structure and culture across the enterprise
- Leverage and reuse technology investments (IT infrastructure, resources and assets) and increase operational efficiencies
- Consider system enhancements that improve client/consumer experience for enterprise applications
- Ensure coordination among projects when DDI efforts cross multiple agencies
- Provide HCA with the authority and the information needed to effectively perform their role as the State's Single Medicaid Agency
- Ensure enterprise compliance with federal Medicaid requirements/guidance

The State has implemented a four-tiered governance structure:

Level 1: **Executive Sponsor Committee** provides the mechanism by which Medicaid Enterprise investments are vetted, approved, prioritized and monitored through their lifecycle by providing strategic insight, cross-organizational project support and federal funding guidance across Washington's health and human services enterprise.

Level 2: **Enterprise Steering Committee** ensures business alignment and provides operational direction for enterprise projects in support of the Executive Sponsor Committee

Level 3: **Integrated Enterprise Project Group** brings Project Management functions from the organizations/agencies together to ensure holistic project coordination with an Enterprise view of projects with a cross-agency Medicaid system impact.

Level 4: **Project Delivery Teams** are agency-sponsored and responsible for operational and tactical oversight of a specific project.

All activities of this P/I APD will be governed by the HHS Enterprise Coalition from a strategic perspective. The initiation of these activities has been approved as being in alignment with the goals of the enterprise. While the operational processes are currently being defined, it is anticipated that the enterprise would review and provide oversight of the activities in this P/I APD. If needed, this includes Independent Verification & Validation (IV&V) by the enterprise's IV&V contractor. Enterprise governance will support addressing cross-enterprise issues and risks associated with these activities.

4.1.2 DOH Steering and Governance

In addition to the steering and governance provided by the HHS Enterprise Coalition, DOH has agency-specific structures and processes that will support the success of the DOH activities in this P/I APD. DOH is committed to effective management of information technology (IT) in support of public health programs and services. New technology offers capabilities that are needed to fulfill the agency mission and goals. DOH has established an IT Governance Group to oversee all aspects of Information Technology projects they ensure processes are followed, documented, and approved in compliance with requirements of the State of Washington and the Department of Health. The project to implement a new PDMP has been through the required Department of Health Project Initiation Process. The Project Initiation Process requires business to seek expert assistance from Health Technology Solutions in the development of project proposal documentation which is complete. Together, they assessed the risk and impact using the IT Project Assessment (ITPA) Tool to determine the level of Washington State Office of the Chief Information Officer (OCIO) visibility/oversight. A Business Case has been submitted to the IT Solutions Team for analysis and development of recommend solution options and cost estimates. A decision paper has gone before the agency IT Governance Group for scoring and a decision has been made to add the project to the agency queue. Based on the results of the ITPA, external quality assurance may be engaged and OCIO oversight initiated. Once the project is active, the DOH Chief Information Officer partners with the Executive Sponsor to manage resources and sits on the Project Steering Committee.

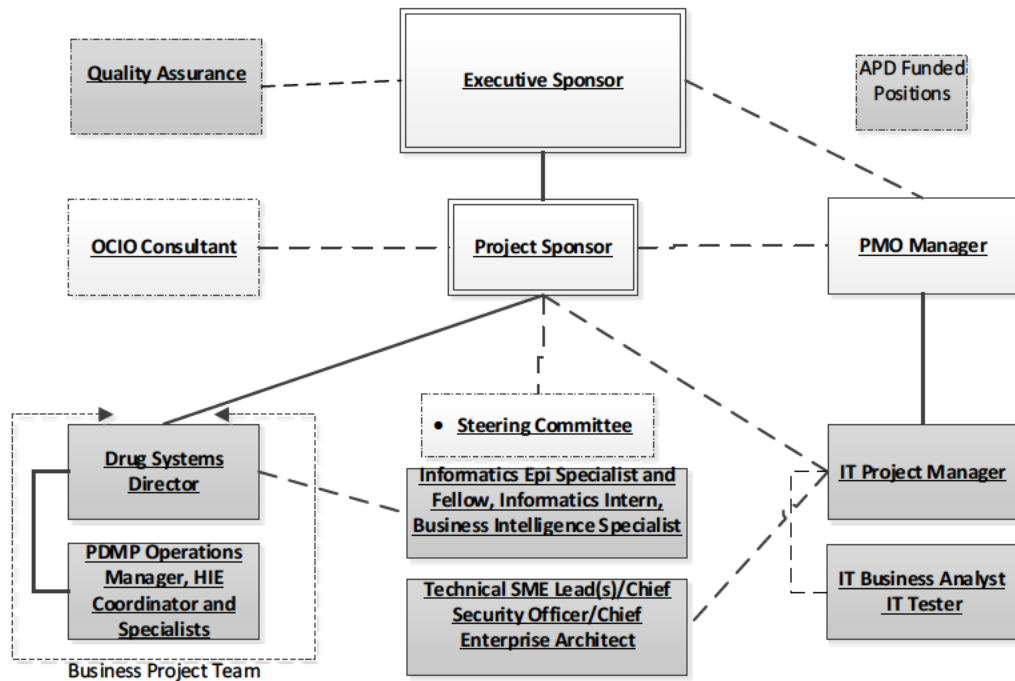
The day-to-day oversight of the PDMP project will be conducted at DOH by an Executive Sponsor and Project Steering Committee within the Health Systems Quality Assurance Division. This project will be governed by a formal charter and will meet regularly to oversee project progress. DOH is planning to procure external quality assurance to provide additional oversight and to help ensure project success.

4.2 DOH Personnel Resources

To support the planning, procurement and implementation phases for the PDMP Project, DOH proposes the following personnel resources to develop functional and technical requirements for the Request for Proposal (RFP), conduct the procurement, and implement the new PDMP.

The resources identified in this estimate were derived from the CoCoMo-II and CoCOTS estimation tools and techniques. These incorporate a set of scale factors (development flexibility, architecture/risk, team cohesion, precedent, personnel capability, personnel experience and process maturity) that identify specific characteristics of staff, the team, the desired solution and the current state of factors such as requirements and level of documentation available. Resource requirement estimates are generated by the tool. These hours have been evaluated by business and it has been determined that the business unit(s) have adequate capacity to accomplish the effort in the timeframe required through use of this and other funding sources.

DOH will be hiring additional IT staff resources to ensure existing staff who are at capacity are not required to complete this project. This will initially involve hiring an IT Project Manager and a Business Analyst. They will ensure the selected vendor has a solid project plan in place that is being followed, monitor the budget and ensure requirements are properly defined and tested.



4.2.1 Project Roles and Responsibilities

The table below describes the DOH project oversight roles and responsibilities.

Project Team Role	Responsibilities
Project Steering Committee	<ul style="list-style-type: none">• Approve charter by consensus• Identify, secure, and assign project resources• Assist the project sponsor in shaping the project vision and objectives• Advise the project sponsor on matters pertaining to scope and schedule• Attend regular meetings to address policy questions, issues, risks, and concerns identified by the project• Determine appropriate changes to organizational policy as identified by the project• Set priorities and resolve issues as suggested by the project sponsor• Represent the interests and concerns of stakeholders and their organizations or constituents• Track issues that may affect stakeholders and their organizations• Communicate project status and outcomes to internal and external stakeholder groups

Project Team Role	Responsibilities
Executive Sponsor	<ul style="list-style-type: none"> • Ensure funds and resources are available when the project needs them • Generate support from internal and external stakeholders • Approve changes that are beyond the project sponsor's decision boundaries for political support, scope, schedule, budget, or quality • Lead cross agency, division, and program problem resolution • Ensure the decision making process for escalated issues is quick and effective • Direct project sponsor, project managers, and steering committee as needed • Communicate project status and importance to internal and external stakeholders • Ensure alignment of project outcomes to strategic and business operation requirements • Ensure the project achieves stated benefits • Remove political barriers that may arise during system implementation • Provide resources necessary for project success • Resolve high-level issues related to project scope, budget, resources, or policy decisions as appropriate • Approve project deliverables as appropriate • Identify issues and risks, and assist with resolution or mitigation • Approve changes that affect project scope, schedule, budget, or quality • Drive project policy decisions
Project Sponsor	<ul style="list-style-type: none"> • Define the business vision and value for the solution • Ensure the project supports strategic business objectives • Ensure funds and resources are available when needed • Ensure decision making for escalated issues is quick and effective • Ensure the project achieves stated benefits • Approve project deliverables • Offer organizational, political, and financial support to the project • Report project status to executive sponsor • Assist in communicating project status and importance to internal and external stakeholders • Identify issues and risks, and assist with resolution or mitigation
PMO Manager	<ul style="list-style-type: none"> • Provide project management guidance and support • Supervise and support IT Project Manager • Identify issues and risks, and assist with resolution or mitigation

Project Team Role	Responsibilities
OCIO Management Consultant	<ul style="list-style-type: none"> • Provide project sponsors with an independent assessment of issues as needed, and make recommendations to address issues • Identify concerns related to project performance and success • Ensure that the project follows state policies and standards
Quality Assurance Contractor	<ul style="list-style-type: none"> • Provide project sponsors with an independent assessment of issues as needed, and make recommendations to address issues • Provides: Quality Assurance Management Plan, Initial project Risk assessment report, Readiness Assessment, reoccurring QA reports, project close out with Lessons learned at a minimum. • Provide consultative support • Review project documentation • Perform monthly reviews of project progress • Identify concerns related to project performance, success and in support of DOH and state OCIO policies. •

The table below describes the DOH PDMP Project Team roles and responsibilities

Project Team Role	Responsibilities
IT Project Manager	<ul style="list-style-type: none"> • Manage the day-to-day technical tasks of the project • Ensure that all technical team members understand their roles and responsibilities and are fulfilling those duties satisfactorily • Coordinate activities between DOH IT and business • In coordination with the business project manager: <ul style="list-style-type: none"> • Support development of the project charter, management plan, and work plans • Manage project's scope and schedule • Manage issue documentation and resolution • Manage risk and risk mitigation strategies • Manage the deliverable review process to ensure that deliverables meet organizational goals and objectives • Communicate project status to sponsors and stakeholders

	<ul style="list-style-type: none"> • Monitor and report the overall project status per the communication plan • Determine project resource requirements and enlist stakeholder support to obtain these resources • Manage project artifacts • Ensure project compliance with state and agency policies and guidance • Manage RFP and related contracts process and budgets • Plan and lead team meetings • Identify issues and risks, and assist with resolution or mitigation • Facilitate the escalation of high-level issues to the project sponsor and executive sponsor as appropriate
IT Business Analyst (BA)	<ul style="list-style-type: none"> • Determine BA project resource requirements and work with BA Supervisor and project manager to secure these resources. • Maintain requirements documentation and manage changes • Identify issues and risks, and assist with resolution or mitigation • Promote project collaboration and transparency. • Collaborate requirements with testing to support timely and complete testing coverage
IT Tester	<ul style="list-style-type: none"> • Develop test cases • Develop test plan • Perform system testing • Coordinate testing including User Acceptance Testing
Technical Subject Matter Expert (SME) Leads	<ul style="list-style-type: none"> • Manage tasks associated with technical requirements. This includes but is not limited to work related to: enterprise architecture, rhapsody engine, and secure access Washington. • Elicit input from appropriate SMEs and represent their input to project deliverables. • Ensure quality of technical requirements deliverables. • Identify issues and risks, and assist with resolution or mitigation. • Promote project collaboration and transparency.

<p>Chief Security Officer</p>	<ul style="list-style-type: none"> • Identification of the scope of the system or solution to be implemented • Providing non-functional requirements (security) • Contributing to the development of a contractual agreement with selected solution provider • Completion of the Office of Cyber Security (OCS) design review workbook • Review the system architecture • Identify the business impacts (if any); this is DOH's risk assessment • Determine the appropriate risk ratings for the solution • Inventory and validate the required security controls (administrative and technical) • Conduct the formal OCS design review • Review the security controls and any OCS action items • Coordinate / Conduct security control testing • Develop and provide assessment findings, security recommendations and risk ratings • Prepare and submit the executive summary report (system authorization).
<p>Chief Enterprise Architect</p>	<ul style="list-style-type: none"> • Manage, translate architectural requirements and design information system architecture for IT solutions. Provide consultation on ideal future state IT infrastructure. Design and develop the DOH vision that underlies the projected solution and transforms that vision through execution into the solution.
<p>Drug Systems Director</p>	<ul style="list-style-type: none"> • Manage the day-to-day business tasks of the project • Coordinate activities between business and DOH Health Technology Services • In coordination with the IT project manager: <ul style="list-style-type: none"> • Support development of the project charter, management plan, and work plans • Manage project's scope and schedule • Manage issue documentation and resolution • Manage risk and risk mitigation strategies • Manage the deliverable review process to ensure that deliverables meet organizational goals and objectives • Communicate project status to sponsors and stakeholders • Monitor and report the overall project status per the communication plan

	<ul style="list-style-type: none"> • Determine project resource requirements and enlist stakeholder support to obtain these resources • Manage project artifacts • Ensure project compliance with state and agency policies and guidance • Manage RFP and related contracts process and budgets • Plan and lead team meetings • Identify issues and risks, and assist with resolution or mitigation • Facilitate the escalation of high-level issues to the project sponsor and executive sponsor as appropriate • Manage the project budget and spending plan
PDMP Operations Manager	<ul style="list-style-type: none"> • Provide business subject matter expert input on project activities and feedback on deliverables • Assist with project communication and training activities • Collaborate with program area subject matter experts • Identify issues and risks, and assist with resolution or mitigation
PDMP Specialists (3 FTE)	<ul style="list-style-type: none"> • Provide business subject matter expert input on project activities and feedback on deliverables • Assist with project communication and training activities • Collaborate with program area subject matter experts • Identify issues and risks, and assist with resolution or mitigation
PDMP System Support Coordinator	<ul style="list-style-type: none"> • This position serves as the PDMP help desk manager for data compliance and end user support. This position will oversee the help desk operation to ensure the highest level of service is provided to health providers. Provides help desk technical support, and/or responds to trouble reports from users and identifies and resolves problems.
PDMP Health Information Exchange (HIE) Coordinator	<ul style="list-style-type: none"> • Assist in defining requirements and performing UAT for the new PDPM system.
Informatics Epidemiologist	<ul style="list-style-type: none"> • Perform data validation, provisioning, and analysis for the performance metrics required under the SUPPORT Act and for the

Specialist (5 FTE)	other DOH opioid related data sets (PDMP, vital statistics, drug user health program and Injury and Violence Prevention).
Informatics Epidemiologist Fellow	<ul style="list-style-type: none"> This position provides long-term technical assistance to the PDMP and Opioid Analytic Platform. Specific projects will be identified during the recruitment, but these pre or post doc fellows will apply expertise in information science, computer science, and information technology to support subject matter experts. This may include integrating the Healthcare Enterprise demos at Health Information and Management Systems Society.
Informatics Intern(s)	<ul style="list-style-type: none"> This position provides short-term technical assistance to the PDMP. Specific projects will be identified during the recruitment, but these interns will apply expertise in information science, computer science, and information technology to support PDMP subject matter experts. This position will support developing updated implementation guides for transacting PDMP data through the HIE (HL7/NCPDP/FHIR/Rhapsody). This may include IHE demos at HIMSS. This may be used by different interns each quarter.
Business Intelligence Specialist	<ul style="list-style-type: none"> This position will work to build the required data reports and visualizations in DOH's enterprise platform for the data that are required for tracking performance metrics under the SUPPORT Act.

4.3 HCA Project Roles and Responsibilities

The table below describes the roles and responsibilities for HCA consulting resources

Project Team Role	Responsibilities
Consent Management Project Manager	<ul style="list-style-type: none"> Manage the day-to-day tasks of the consent management project Support development of the project charter, management plan, and work plans Manage consent management project's scope and schedule Manage issue documentation and resolution Manage risk and risk mitigation strategies Manage the deliverable review process to ensure that deliverables meet organizational goals and objectives Communicate project status to sponsors and stakeholders

- Communicate with federal partners as necessary to report scope changes and ensure compliance with funding requirements for consent management activities
- Monitor and report the overall project status per the communication plan
- Determine project resource requirements and enlist stakeholder support to obtain these resources
- Manage project artifacts
- Ensure project compliance with state and agency policies and guidance
- Plan and lead team meetings
- Coordinate with state IV&V vendor on project success measurement
- Develop project close-out materials that assess the current state of electronic consent management adoption, and provides a proposal for future phases of stakeholder engagement and adoption

In addition to the contracted resources described above, existing HCA staff will also support the HCA initiatives of this P/I APD. The state staff resources described in the HIT IAPDU-11 will be the primary state resources to plan and implement the HCA initiatives of this P/I APD. This P/I APD does not request any funding for HCA state staff resources. Please refer to the HIT IAPD update 11 submitted to the HITECH mailbox on March 5, 2018 for further details on the HCA staff that will support the HCA initiatives of this PDMP P/I APD.

The eleventh update to Washington’s Health Information Technology IAPD (HIT IAPDU-11) was approved by CMS on April 25, 2018 with funding approved through September 30, 2019. No later than June 2019, HCA will be submitting another update to the HIT IAPD to request funding in FFY 2020 for state staff that will continue to support all initiatives of the HIT IAPD, including the HCA initiatives of this PDMP P/I APD.

5. Project Management

5.1 Workplan and Project Schedule

The provided schedule for the PDMP procurement and implementation is the best estimate (given limited information) considering input from program, IT office, and procurement. However, the schedule will be reassessed during contract negotiations with the PDMP Apparently Successful Bidder (ASB). DOH recognizes that some of the dates extend past the end of the Support Act. As such, the contract will identify payment amounts for milestone deliverables that could be completed prior to the end of Federal Fiscal year 2020.

Summary Deliverables	Projected Timeline
Complete full requirements of system and complete documentation for Request for Proposal (Competitive Bid)	April-October 2019
Data conversion and migration from current PDMP platform to internal analytic environment and potential new vendor.	June 2019 – July 2021
Obtain CMS approval of Request for Proposal (RFP)	November- December 2019
Detailed Requirements and Test Planning	November 2019 - April 2020
Release PDMP RFP, receive and review bids and finalize contract with vendor	January – March 2020
Obtain CMS approval of PDMP contract.	April 2020 – May 2020
Manage development of system with Contractor utilizing methodologies and technology consistent with interoperability with shared services and central data portal (HIE), to include business analysis of partners' readiness to access state HIE via their EMR systems.	June - December 2020 (June – September 2020 for Vendor COTS) (June– December 2020 for WA Customization)
Testing of developed system and continued development for defect corrections to comply with all program requirements, including interoperability, and connecting providers who are business ready.	November 2020 – May 2021
Training of internal staff and reporting partners in use of system.	June - July 2021
Formal launch of system	August 2021

Ongoing technical assistance efforts until all reporters are using the system.	May 2019 and ongoing
Monitor and refine system based on initial launch. Implement any enhancements needed, especially as federal standards evolve.	Ongoing
Obtain CMS approval of an interagency agreement with University of Washington to provide technical assistance to providers	June – July 2019
Execute contract with ISDS for joining their opioid overdose data to action community of practice project.	June – July 2019
Obtain contractor for external Quality Assurance.	June - July 2019
Obtain CMS approval of Consent Management Request for Proposal (RFP)	July - August 2019
Release Consent Management RFP, receive and review bids, and finalize contract with vendor	September – November 2019
Obtain CMS approval of Consent Management Contract	December 2019 – January 2020
Develop and test Consent Management technology solution	February 2020 – April 2020
Implement Consent Management system, conduct internal and pilot adopter workflow integration and technical assistance.	May 2020 – June 2020
Formal Consent Management Launch	July 2020
Additional Consent Management integration efforts, technical assistance, and agile system improvement	August 2020 – September 2020
Consent Management system monitoring	September 2020 – TBD

Sustainability/Contingency Funding:

For PDMP implementation activities not completed by September 30, 2020, DOH has two potential options for funding in FFY 2021:

- a Department of Justice (DOJ) grant that can be used to help fund a portion of the remaining implementation costs.
- a funding request is included in the Governor’s proposed budget for the 2019-2021 biennium. If funding for the DOH request is included in the enacted budget, the funds would provide the state match for an FFY 2021 Implementation APD to request Medicaid funding at 90 percent Federal Funding Participation (FFP) for any remaining PDMP DDI costs not funded by the DOJ grant.

5.2 Procurement and Solicitation Activities

HCA and DOH are proposing the following procurements to support the implementation of a PDMP and other tools described in this Planning/Implementation APD that will be integrated with the PDMP to address the opioid crisis.

5.2.1 PDMP Vendors

DOH intends to conduct a competitive procurement to purchase a PDMP system for future use. Information gathered from other states' Prescription Drug Monitoring Programs indicates that there may be other service providers in the market that offer similar or improved systems at competitive prices.

DOH also plans to contract with a vendor to migrate data into DOH's opioid analytic environment. This could occur independently from the RFP for a new system.

5.2.2 Quality Assurance

DOH will conduct a competitive procurement for Quality Assurance (QA) services. The QA vendor will provide the Project Executives, Project Managers, and Stakeholders with timely, independent, and objective reviews of the Project. The reviews will provide reliable information to those charged with oversight of the project. The outcome of a QA review is the early identification and mitigation of risks that might otherwise diminish the success of the project. This is a requirement based on Office of the Chief Information Officer policies for IT projects.

5.2.3 Technical Assistance

DOH plans to execute an interagency agreement with University of Washington (UW) to provide technical assistance to providers to assist in integrating PDMP data at the point of care (providers Electronic Health Record System) and to conduct evaluations to determine which approach(es) are the most successful for replication. While the objective for all involved sites will be successful deployment of the PDMP with workflow at the point of care, if this is not possible, UW will seek to understand the major barriers for this use case to inform future work. The scope of work will include the following tasks:

- Conducting a thorough evaluation of how this connectivity into workflow is and is not working and comparing this to work done in other states for such connectivity;
- Research, development and demonstration of a PDMP Fast Healthcare Interoperability Resource (FHIR) module for piloting with the HIE; and
- Conducting an evaluation of the current Tableau opioid dashboard to enhance its usability and value to DOH and its partners in addressing the opioid crisis. Also provision of technical assistance to DOH to assist in implementing recommended changes.

In the past, UW has collaborated with Qualis Health (the former Washington Regional Extension Center for HITECH) for similar work and would likely subcontract with them to support the work of this agreement. This work can begin immediately following CMS approval with the current PDMP as

it involves integration through the state HIE. Using modular architecture, if a new PDMP vendor is selected and a new system put in place, customers connected to the HIE will not have to do any new work as the HIE uses a national standard for the data connection and using the HIE for their connection point. This will be essential given new state rules in place that require a PDMP check prior to prescribing and the new SUPPORT Act requirement for Medicaid providers to check the PDMP.

5.2.4 Independent Verification and Validation (IV&V)

In 2018, HCA conducted a competitive procurement for IV&V services for the WA State Medicaid Enterprise and executed contract K2570 with Public Knowledge, LLC. Prior to execution, the contract was approved by CMS on October 31, 2018. The initial Statement of Work (SOW) is for Medicaid Eligibility and Enrollment projects. The contract scope states that additional SOWs may be entered into between the parties to describe IV&V services and Project Deliverables for additional Medicaid Management Information System (MMIS) or Eligibility and Enrollment (E&E) projects for new or replacement modules or modifications to existing systems during the term of the Contract.

IV&V requirements for the PDMP project have not yet been determined. In the event the PDMP project requires IV&V services, HCA will execute an amendment to contract K2570 to add a SOW for IV&V services for the PDMP project.

5.2.5 Rhapsody

Rhapsody is used to route data for several opioid data sets. To support the opioid work, DOH requires more communication points to have the bandwidth needed for this new work. DOH is requesting funding for the new communication points and incremental costs of annual licensing fees. DOH will also be contracting with Rhapsody Health, Inc. for Rhapsody (DOH Enterprise Interoperability Engine) training and certification to train DOH opioid subject matter staff in preparation of implementation of the PDMP and in linking PDMP data with other opioid data sources. The department will also be including funding with Rhapsody for consulting services around establishing the new, integrated opioid analytic environment.

5.2.6 International Society for Disease Surveillance (ISDS)

DOH will be executing a sole source contract with ISDS and/or the Public Health Informatics Institute (PHII) for joining their opioid overdose data to action community of practice project. This would be a central hub for sharing best practices for analyzing a variety of data sources, and would involve a multitude of stakeholders. This would enhance DOH's ability to use best practices in setting up our shared opioid analytic environment. Funding would provide the following deliverables:

- An annual, on-site, in person, 2-day, customized training;
- Facilitated quarterly calls for the department and our partners to improve coordination, share best practices and identify gaps; and
- Provide access to the ISDS/PHII knowledge repository including tools, resources and an active forum.

5.2.7 Project Management Consulting

HCA will procure the consulting services by conducting a second tier competition under HCA's pool of Health Consulting Contracts, in compliance with state of Washington procurement laws and policies. The competitive process will result in a Work Order (statement of work) under the bidder's existing Health Consulting Services Contract, which will be incorporated into the contract.

5.2.8 Professional Services to implement HCA initiatives

As part of the planning phase, HCA will determine the procurement strategy for services to implement the HCA initiatives for availability of additional clinical data sources and reporting for clinical and case management. If applicable, HCA will consider leveraging the current contract with OneHealthPort for Clinical Data Repository services.

5.2.9 Consent Management Solution

HCA will perform a competitive procurement for an electronic Consent Management solution. It is expected that the vendor will consult with internal state resources, state-designated health information exchange representatives, and community provider groups and associations in order to design and develop a consent management solution that can be uniformly utilized to exchange data to support clients with opioid and substance use disorders. The contractor will be required to develop the system in conjunction with state and external requirements, solicit feedback from the impacted provider community, and incrementally develop the solution based on feedback during implementation, workflow integration, and deployment sessions led and managed by the contractor in coordination with HCA. Contractor is responsible for technical assistance for providers and their EHR and other system vendors during the development and implementation phases of the project.

6. Proposed Project Budget and Cost Distribution

6.1 Estimated P/I APD Budget

The budget request for the P/I APD period ending September 30, 2020 is \$11,212,798.

Cost Category	FFY 2019	FFY 2020	Total
DOH Personnel (Salary & Benefits)	\$382,102	\$2,008,022	\$2,390,124
PDMP Vendors	\$0		
QA Contractor	\$0		
IV&V Contractor	\$0		
Rhapsody	\$0		
ISDS Contract	\$0		
Travel	\$30,000	\$90,000	\$120,000
DOH Indirect and Misc. Costs	\$117,092	\$807,782	\$924,874
Subtotal for PDMP Implementation	\$529,194	\$4,853,604	\$5,382,798
Consulting – Technical Assistance			
Consent Management Solution			
Professional Services for HCA initiatives ¹			
Project Management Consulting			
Total for all PDMP Activities	\$1,119,194	\$10,093,604	\$11,212,798

DOH Travel Costs

Travel budget includes important conferences like HIMSS IHE, National Interoperability Consortium, PDMP/NCPDP/RxCheck, CSTE and PHI conferences for demo and testing of PDMP and NCPDP standards testing that will assist DOH in understanding how to best implement the new system.

DOH Indirect & Miscellaneous Costs

DOH uses the “provisional rate” method of indirect rates in accordance with [2 CFR 200 Appendix VII](#). The Department of Health and Human Services (HHS) approves DOH’s provisional rates each fiscal year.

There are two types of approved indirect cost rates used at DOH:

Pass-through rate of 1.4 percent on costs for contracts and subcontracts

Divisional indirect rates applied to all other allowable direct costs excluding contracts/subcontracts. There are five different rates that may be used depending on which DOH division incurred the costs.

The rates approved for State Fiscal Year (SFY) 2020 (from 7/1/19 to 6/30/20) are:

- 27.00% for Disease Control and Health Statistics
- 27.90% for Environmental Public Health
- 28.20% for Health Systems Quality Assurance
- 30.50% for Prevention and Community Health
- 16.90% for Central Administration

Other costs are excluded from the HHS approved SFY 2020 indirect cost plan and the costs are allocated as follows (rates for SFY 2020 are not yet available; the rates shown below are for SFY 2019):

- Rent/Utilities \$464 per workstation per month
- Enterprise Software/Email: \$85 per FTE per month
- Campus Cost Allocation (IT support) \$126 per FTE per month
- Telephone \$23.50 per workstation per month

6.2 State Personnel

DOH Personnel Costs

POSITION	Hours FFY 2019	Funding FFY 2019	Hours FFY 2020	Funding FFY 2020
IT Project Manager	697	\$ 43,885	2,080	\$ 131,000
IT Business Analyst	348	\$ 19,933	1,040	\$ 59,500

IT Tester	88	\$ 4,548	1,040	\$ 53,500
Technical SME Lead(s)	858	\$ 54,012	5,920	\$ 372,846
Chief Security Officer	57	\$ 3,861	100	\$ 6,779
Chief Enterprise Architect	94	\$ 7,215	140	\$ 10,769
Drug Systems Director	52	\$ 3,543	157	\$ 10,628
PDMP Operations Manager	348	\$ 17,085	1,040	\$ 51,000
* PDMP Specialist(s) - 3	2090	\$ 69,345	6,240	\$ 207,000
* PDMP System Support Coordinator	697	\$ 31,155	2,080	\$ 93,000
Informatics Epi Fellow	177	\$ 8,925	2,080	\$ 105,000
Informatics Intern	697	\$ 23,115	2,080	\$ 69,000
PDMP HIE Coordinator	697	\$ 32,495	2,080	\$ 97,000
* Informatics Epi Specialist	884	\$ 51,850	10,400	\$ 610,000
Business Intelligence Specialist	177	\$ 11,135	2,080	\$ 131,000
TOTAL:	7,961	\$ 382,102	38,557	\$ 2,008,022

* These positions are also funded under HITECH IAPD. They are listed here so that their contribution to the implementation of a new PDMP is included in the funding request of this P/I APD. Time tracking will separately designate the actual hours worked on activities of this P/I APD from the actual hours worked on other PDMP activities described in the HITECH IAPD to ensure the claim of federal funding is not duplicative.

All of the proposed staff listed above are employees of the Washington State Department of Health; none of these personnel provide services as a contractor or third party vendor.

6.3 Cost Allocation Plan and/or Methodology

H.R. 6 - SUPPORT for Patients and Communities Act became law on October 24, 2018. It includes several provisions related to Prescription Drug Monitoring Programs (PDMPs), including Section 5042 that creates a Medicaid requirement for a “qualified PDMP” and makes available for a time limited basis (October 1, 2018 to September 30, 2020) 100 percent Federal Medical Assistance Percentage (FMAP) for expenditures for a qualified PDMP. With this provision available the State of Washington does not need a cost allocation plan for the budget requested for FFY 2019 and FFY 2020.

7. Period of Use

The initial period of performance of any contract(s) resulting from this Solicitation would be the vendor proposed design, development, and implementation plus 5 years for maintenance and operations. The DOH reserves the option at its sole discretion to extend the contract for an additional 5 years for maintenance and operations at increments that the department deems appropriate. Any amendment to exercise the option to extend the contract period will meet CMS prior approval requirements.

8. Statement of Security/Interface and Disaster Recovery Requirements

The PDMP solution put forth in this P/I APD aligns with the DOH Enterprise Technology Strategic Plan by following the premise of capturing data once and using it many times with a single record of truth and by leveraging data resources from other internal and external sources to support the overall business needs. Evaluations are performed to determine if the solution can increase capacity to manage and share information.

If a Commercial off the Shelf or SaaS product is sought the vendor is expected to accurately and fully disclose all materials that support the evaluation of all products used to construct and support the product. Penetration testing is a requirement. All solutions are evaluated to determine if the publishing of data to the Open Data site is appropriate and in the best interests of the agency and the public. A strict set of criteria has been established by the agency to assess risk and to assist in the identification of data that should be published. Reuse, integration and interoperability assessments are conducted to determine the viability of each for current and future implementation. Assessments and design consideration is given to all components to identify opportunities for standardization and reuse. All products are assessed for accessibility.

Since the PDMP system will contain category 4 data (confidential patient health care information), DOH will require all state and agency security standards to be met by the service provider. PDMP data are currently published to the open data portal in anonymized form. Any system will be required to continue production of an anonymized data file for the open data portal.

The PDMP system is listed as a mission critical system for the Washington State Department of Health. Therefore any contract for the system will require a disaster recovery and business continuation of operations plan. The system must have redundant backups at multiple locations in the United States for recovery and must maintain 24/7 uptime with a 98 percent success rate.

Data contained within the Consent Management application will also be considered category 4 data, and HCA will require all state and agency security standards to be met by any successful vendor. All databases, interfaces, and access points will be required to comply with state requirements for availability, security, and disaster recovery.

The Consent Management solution will be expected to follow HIPAA and HITECH privacy and security requirements while interfacing with the state designated health information exchange and clinical data repository. Both of these services have been assessed for security risks and comply with statewide data security and availability requirements. These services will be leveraged as part of the planning for the integrated data solutions and report products produced in combination with PDMP data made available through the Department of Health system.

9. CMS Required Assurances

The state assures compliance with the following:

Procurement Standards

CMS Rules & Regulations		
SMM Section 11267	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
45 CFR Part 95.615	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
45 CFR Part 92.36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

Access to Records

CMS Rules & Regulations		
42 CFR Part 433.112(b)(5) – (9)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
45 CFR Part 95.615	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
SMM Section 11267	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

Software & Ownership Rights, Federal Licenses, Information Safeguarding,

HIPAA Compliance* and Progress Reports:

CMS Rules & Regulations		
45 CFR Part 95.617	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
42 CFR Part 431.300	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
45 CFR 164 Securities and Privacy	<input checked="" type="checkbox"/> Yes*	<input type="checkbox"/> No

IV&V

CMS Rules & Regulations		
45 CFR Part 95.626	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

* Washington DOH is a hybrid entity for the purposes of HIPAA. The agency's single healthcare component is not involved or implicated in this special project application. For the purposes of this special project Washington DOH is a public health authority under 45 CFR s. 164.512 and is not a Covered Entity or Business Associate as defined under 45 CFR s.160.103.

Washington DOH security and privacy practices are consistent with 45 CFR 164 except for the following:

- In Washington DOH's role as a Public Health Authority, it does not require nor sign Business Associate Agreements. Washington DOH contracts and agreements include security and privacy requirements that are consistent with state and federal security and privacy regulations.

10. Compliance with Enhanced Funding Requirements

PDMP planning and implementation efforts are consistent with the standards and conditions as outlined in 42 CFR §433 Subpart C.

1. **Modularity:**

WA DOH is currently investing HITECH funding to enhance its Meaningful Use Architecture. DOH utilizes Orion Health's Rhapsody product as the Enterprise Interoperability Engine to receive process and acknowledge HL7 2.5.1 and CDA messages between Public Health Providers and several DOH registries. Rhapsody is a software platform that follows interoperability standards and is a Modular Certified Health IT product for the Public Health Meaningful Use Measures. In selecting a product for the PDMP solution DOH will require interoperability with Rhapsody and/or the health information exchange as a solution requirement. Modular connectivity to the Medicaid Enterprise MMIS will be determined as part of the Medicaid enterprise coalition work to include open interfaces and exposed Application Programming Interfaces (API). One key component is an API to interact with the yet to be determined master person index solution for the health and human services enterprise.

The Consent Management service that HCA will contract for is expected to be an independent module in the health information exchange ecosystem, decoupled from other major services such as the CDR or the PDMP. It will interact with these other services in a standards-based manner, but be technologically separate in order to preserve independence of the systems. This will put HCA in a better competitive position for any procurements or replacements of these key health information systems. The efforts for additional data sources and decision-making tools will also support modularity requirements by ensuring that the technologies work with multiple platforms in an efficient and interoperable way.

2. **MITA:**

The PDMP is a continuation of funded Medicaid HITECH Investments in the PDMP and will advance MITA maturity for business, architecture and data. As per the State Medicaid Director Letter (SMDL # 18-006) PDMP functionality is now explicitly included in the MITA framework. DOH anticipates the PDMP registry to fit under the MITA framework similar to the immunization registry as a modular functionality that can exist outside of the State Medicaid Agency. Under HITECH, DOH has been operating with PDMP under the Public Health Specialized Registry category. The new PDMP will be included in the MITA Roadmap at the next regular update.

The Consent Management service and the enhancements to the CDR data sources and reporting capability help HCA increase MITA maturity by improving the breadth of information which can be collected by the Medicaid enterprise, used for improved outcome measurement and population management, and exchanged between the Medicaid enterprise and external partners. These efforts support and improved Medicaid IT ecosystem.

3. **Industry Standards:**

WA DOH will comply with all applicable federal standards for which public health reporting is not excluded. This includes following ISA requirements to use NCPDP for PDMP Transactions (<https://www.healthit.gov/isa/allows-a-prescriber-request-a-patients-medication-history-a-state-prescription-drug-monitoring>).

The Consent Management service and the enhancements to the CDR data sources and reporting capability will be designed to utilize and reinforce industry standards regarding authentication, interoperability, HL7 conformance, and other standards within the ISA related to access, transmission, and use of health information.

4. Leverage Condition:

WA DOH will leverage all possible technologies including other federally funded investments in Washington State such as use of the state Health Information Exchange (HIE) and DOH's interoperability engine. DOH intends to continue to connect to the federal funded RxCheck hub as well to provide interstate data sharing. DOH has received letters of support from Washington's contiguous states (Oregon and Idaho) to meet the SUPPORT act requirements for funding at 100 percent FMAP. DOH has also signed an MOU to join the PMPi Hub which Oregon and Idaho have already signed onto for interstate data sharing.

The Consent Management service will leverage existing technologies within the State health information sharing ecosystem, such as the HIE and the CDR, which both leverage existing information available through provider EHR systems and state MMIS technology. There are additional opportunities to leverage consent management throughout the enterprise once the system has been deployed and integrated into provider workflow. For example, the system could be utilized to support patient direction of data sharing for programs, and enhance the information available for quality and performance reporting. The enhancements to the CDR data sources and reporting capability leverage existing investments in the CDR, and interface with existing services that support the exchange and use of health information to and from provider certified EHR technology.

5. Business Results:

N/A – The PDMP system is not a claims/ claims of eligibility/adjudications application.

The Consent Management service and the enhancements to the CDR data sources and reporting capability will not directly impact the accurate and timely processing of claims, but will support effective communications related to providers and beneficiaries regarding the access, sharing, and use of their information.

6. Reporting:

The PDMP system will be integrated with the overall process for Quality Assurance in the Department of Health's Division of Performance and Accountability. DOH will comply with all reporting requirements listed in section 5042 of the Support Act. The current PDMP receives monthly counts of HIE transactions. These are used to track progress and would continue to be used in a new solution. The current PDMP provides quarterly data to track outcome metrics in

DOH's Tableau platform. With a new solution, the goal would be to provide these metrics monthly or weekly.

The Consent Management service will require ATNA-compliant transaction logging which supports program evaluation, continuous improvement, transparency, and accountability. The CDR already supports strict transaction logging and evaluation, and the enhanced reporting and data collection activities will be included in this robust transaction logging service. These services will meet all HIPAA, HITECH, Washington State, and industry standard transaction logging and monitoring to ensure effective evaluation and control of system activities.

7. Interoperability:

The PDMP system currently integrates with the Statewide HIE, using ISA recognized standards (NCPDP), and would continue to do so under the new requirements in the RFP produced. The system uses interoperability standards now (ASAP, NCPDP 10.6) and would continue to do so in the future (ASAP, NCPDP 2017071, and FHIR). Further, DOH is currently exploring connecting PDMP to other opioid related systems in its agency (e.g. Emergency Medical Services, Death Registry, Hospitalization data, injury and violence prevention data, overdose notification).

The PDMP system is not a claims/ claims of eligibility/adjudications application so connectivity to the marketplace is not applicable.

The WA PDMP law allows sharing of data with HCA for Medicaid clients and a data sharing agreement is currently in place that allows HCA clinical staff (including but not limited to the Medicaid Pharmacy and/or Medical Director) to access PDMP data.

HCA, along with the public health agency DOH, and the state health benefit exchange WA HealthPlanFinder, participate in a multi-agency enterprise health IT governance body that will have oversight of the Consent Management and CDR services. This enterprise governance will ensure that the interoperability condition is met as useful/applicable for these services. This will improve coordination with the Exchange, public health, and community organizations.

8. Mitigation Plan:

As part of any DOH approved project, the project manager would build a robust project management plan, change management plan, issue management plan and risk management plan that will help identify, monitor and address strategies to reduce the consequences of failure for milestones and functionality. This will be developed in partnership with the apparently successful vendor and the external quality assurance contractor and submitted to CMS.

HCA will require the vendor for the Consent Management to have a comprehensive project and risk management plan as described in detail by DOH above. For the CDR enhancements, HCA will maintain critical project and risk management in coordination with the CDR and HIE vendor. An expansive risk and issue mitigation plan will be developed for each solution as it is designed.

9. Documentation:

WA DOH intends to purchase a SaaS or BSaaS solution for the PDMP. Per SMDL # 16-009, the documentation requirement does not apply.

HCA will require documentation for the Consent Management solution to be developed and provided by the solution vendor to ensure that the system can be replicated and/or managed as necessary by subsequent vendors or the agency itself. The solution will be procured in a manner where documentation can be distributed external to the Washington State Medicaid enterprise, including to external partners within the state, and other states. Documentation which will be made public will include the request for proposal, project planning documentation, stakeholder engagement and communication documents, workflow and integration mapping, and other relevant documentation.

10. Minimization of Cost for Operation on an Alternate System:

WA DOH performed a solutions analysis of alternative strategies and determined the most cost effective way to meet the program needs was vendor built and hosted solution. Please refer to Section 2: Requirements Analysis / Alternative Considerations above for details.

HCA will ensure that the Consent Management solution is deployed in a modular manner using industry standards and reusable, scalable technology that minimizes the costs and difficulty of operating the software.