SUBMITTAL TO THE RIVERSIDE UNIVERSITY HEALTH SYSTEM MEDICAL CENTER GOVERNING BOARD COUNTY OF RIVERSIDE, STATE OF CALIFORNIA

ITEM: 15.2
(ID # 24619)
MEETING DATE:
Tuesday, April 30, 2024

FROM : RUHS-MEDICAL CENTER:

SUBJECT: RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER: Approve the Professional Service Agreement with Datix (USA) Inc. for DatixWeb to RL6 Platform, without seeking competitive bids, for five years effective upon signature, through April 29, 2029 for the total aggregate amount of $910,198, All Districts. [Total Cost $910,198, up to $91,019 in additional compensation, 100% Hospital Enterprise Fund 40050]

RECOMMENDED MOTION: That the Board of Supervisors:

1. Approve the Professional Service Agreement with Datix (USA) Inc. for DatixWeb to RL6 Platform, without seeking competitive bids, for five years effective upon signature, through April 29, 2029, for the total aggregate amount of $910,198, and authorize the Chair of the Board to sign the Agreement on behalf of the County;
2. Authorize the Purchasing Agent, in accordance with Ordinance No. 459, based upon the availability of funding and as approved as to form by County Counsel, to sign amendments including modifications of the statement of work that stay within the intent of the Agreement and sign amendments to the compensation provisions that do not exceed the total aggregate amount of $91,019 for the term of the Agreement;
3. Authorize the Purchasing Agent to issue Purchase Orders for invoices received for services rendered that do not exceed the total contract amount; and
4. Direct the Clerk of the Board to return three (3) copies of the Agreement to RUHS for distribution.

ACTION:Policy

MINUTES OF THE GOVERNING BOARD

On motion of Supervisor Spiegel, seconded by Supervisor Gutierrez and duly carried by unanimous vote, IT WAS ORDERED that the above matter is approved as recommended.

Ayes:	Jeffries, Spiegel, Washington, Perez and Gutierrez
Nays:	None
Absent:	None
Date:	April 30, 2024
xc:	RUHS-Medical Center

Kimberly A. Rector
Clerk of the Board
By: Naomy Li
Deputy

SUBMITTAL TO THE RIVERSIDE UNIVERSITY HEALTH SYSTEM MEDICAL CENTER GOVERNING BOARD OF DIRECTORS COUNTY OF RIVERSIDE, STATE OF CALIFORNIA

FINANCIAL DATA	Current Fiscal Year:	Next Fiscal Year:	Total Cost:	Ongoing Cost
COST	$220,159	$164,938	$910,198	$0
NET COUNTY COST	$0	$0	$0	$0
SOURCE OF FUNDS: 100% Hospital Enterprise Fund 40050			**Budget Adjustment:** No	
			For Fiscal Year: 23/24 27/28	

C.E.O. RECOMMENDATION: Approve

BACKGROUND:

Summary

In August of 2018 the Riverside University Health System-Medical Center (RUHS-MC) entered into an agreement with Datix (USA) Inc. to use DatixWeb as the source for managing incident reports and improving patient safety. DatixWeb has been effective in handling the needs in which it was intended for, but the web-based reporting site is now becoming obsolete. RUHS-MC therefore needs to migrate to a new system through contract with Datix (USA) Inc.

The RL6 Patient Safety, Risk Management & Quality Improvement Software Solutions offers a streamlined and objective approach for the RUHS-MC Quality Management Department to manage incident reports, conduct peer reviews, and monitor adverse events. Its primary goal is to enhance patient safety and drive performance improvement. With RL6 software, valuable insights will be easily accessible to all stakeholders, promoting transparency and informed decision-making, ultimately resulting in a safer and better experience for physicians, staff, and patients. Although RL6 software is different from Datixweb, Riverside County Information Technology (RCIT) made the determination that H11 approval would not be required for this request due to previous H11 approval of Datixweb and its core similarities to the RL6software.

To comply with regulatory standards set forth by The Joint Commission (TJC) and the Centers for Medicare and Medicaid Services (CMS), all hospitals are required to maintain a confidential event reporting system along with existing voluntary reporting systems. Recommendations from the President's Council of Advisors on Science and Technology (PCAST) summarizes the capabilities of technology and set the standards by which regulatory agencies measure safety compliance. By implementing the RL6 system, RUHS-MC ensures compliance and enable collaborative efforts to compare and benchmark safety data. This new system empowers the quality department to conduct root cause analysis objectively and implement effective risk prevention strategies to reduce patient claims for preventable events and enhance RUHS-MC current Patient Safety Program.

The RL6 system facilitates continuous quality assurance and proactive learning from process failures, errors, or mistakes. This strengthening of our patient safety program will be instrumental in proactively detecting patient safety events and closing the gaps in quality and safety practices. This new system will not only enhance RUHS-MC capabilities but also

demonstrate a strong commitment to patient safety and quality improvement, which will eventually result in cost savings for RUHS-MC.

Impact on Residents and Businesses

These services are a component of RUHS's system of care aimed at improving the health and safety of its patients and the community.

Additional Fiscal Information

There are sufficient appropriations in the Department's FY23/24 budget. No additional County funds are required.

ADDITIONAL FINANCIAL INFORMATION	Year 1	Year 2	Year 3	Year 4	Year 5	Total
COST	$220,159.00	$164,938.02	$169,886.16	$174,982.75	$180,232.23	$910,198.16

Contract History and Price Reasonableness

On April 1, 2024, SSJ number 24-129 was assigned to the single source purchase request for the RL6 platform. RUHS selected Datix USA Inc. to provide RUHS-MC their services because their solutions are aligned with the PCAST recommendations.

RUHS internal Value Analysis Team had a Cost Analysis conducted by the Emergency Care Research Institute (ECRI). ECRI, a third-party vendor, reviews cost item by item, making comparisons based on proposed models and configurations, contract terms, and service costs to ensure that pricing is in line with other government agencies and healthcare facilities. ECRI confirmed that Datix USA Inc. pricing is comparable to other medical centers.

ATTACHMENTS:

Attachment A. SSJ 24-219 MCARC Datix USA Inc Datix USA Inc. Final
Attachment B. SSJ Supporting Attachment Number I
Attachment C. Professional Service Agreement with Datix (USA) Inc. for DatixWeb to RL6 Platform

Jacqueline Ruiz, Principal Analyst 4/23/2024

Gregg Gu, Chief Deputy County Counsel 4/22/2024

PROFESSIONAL SERVICE AGREEMENT

for

DatixWeb to RL6 Platform Upgrade

between

COUNTY OF RIVERSIDE

and

Datix (USA) Inc.

APR 3 0 2024 15.2

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This Agreement is made and entered into by and between Datix (USA) Inc., a Delaware corporation (herein referred to as "CONTRACTOR"), and the COUNTY OF RIVERSIDE, a political subdivision of the State of California, on behalf of Riverside University Health System – Medical Center (herein referred to as "COUNTY" or "RUHS-MC"). The parties agree as follows:

1. Description of Services

1.1 CONTRACTOR shall provide all services, products, and software licenses as outlined and specified in Exhibit A, Scope of Services, at the prices stated in Exhibit B, Payment Provisions, and in accordance with Exhibit C, Software Licensing Terms, and Attachment I, HIPAA Business Associate Attachment of this Agreement .

1.2 Acceptance by the COUNTY of the CONTRACTOR's performance under this Agreement does not operate as a release of CONTRACTOR's responsibility for full compliance with the terms of this Agreement.

2. Period of Performance

2.1 This Agreement shall be effective upon signature of this Agreement by both parties and continues in effect for five (5) years, unless terminated earlier. The Riverside County Board of Supervisors is the only authority that may obligate the County for a non-cancelable multi-year agreement.

3. Compensation

3.1 The COUNTY shall pay the CONTRACTOR for services performed, products provided and expenses incurred in accordance with the terms of Exhibit B, Payment Provisions. Maximum payments by COUNTY to CONTRACTOR shall not exceed $910,198.16 including all expenses. The COUNTY is not responsible for any fees or costs incurred above or beyond the contracted amount. For clarity, County is only being licensed to use the Licensed Materials at Listed Licensed Locations and Unlisted Licensed Locations and up to a specific FTE amount as set forth in Exhibit A. County shall be required to pay additional fees if it uses the Licensed Materials at different locations or if it exceeds the FTE limit.. Unless otherwise specifically stated in Exhibit B, COUNTY shall not be responsible for payment of any of CONTRACTOR's expenses related to this Agreement.

3.2 Pricing for each year is set out in Exhibit B.

3.3 CONTRACTOR shall be paid only in accordance with an invoice submitted to COUNTY by CONTRACTOR within thirty (30) days from the date of receipt of the invoice. Prepare invoices in duplicate. For this Agreement, send the original and duplicate copies of invoices to:

RUHS Fiscal 7888 Mission Grove South, Suite 100 Riverside, CA 92508 or AP@RUHealth.org

a) Each invoice shall contain a minimum of the following information: invoice number and date; remittance address; bill-to addresses of ordering department/division; Agreement number MCARC-92046-050-010/28; quantities; item descriptions, unit prices, extensions, sales/use tax if applicable, and an invoice total.

b) Invoices shall be rendered in advance of services.

3.4 The COUNTY obligation for payment of this Agreement beyond the current fiscal year end is contingent upon and limited by the availability of COUNTY funding from which payment can be made. In the State of California, Government agencies are not allowed to pay excess interest and late charges, per Government Codes, Section 926.10. No legal liability on the part of the COUNTY shall arise for payment beyond June 30 of each calendar year unless funds are made available for such payment. In the event that such funds are not forthcoming for any reason, COUNTY shall immediately notify CONTRACTOR in writing; and this Agreement shall be deemed terminated, have no further force, and effect.

4. Alteration or Changes to the Agreement

4.1 The Board of Supervisors and the COUNTY Purchasing Agent and/or his designee is the only authorized COUNTY representatives who may at any time, by written order, alter this Agreement. If any such alteration causes an increase in the cost of, or the time required for the performance under this Agreement, an equitable adjustment shall be made in the Agreement price or delivery schedule, or both, and the Agreement shall be modified by written amendment accordingly.

4.2 Any claim by the CONTRACTOR for additional payment related to this Agreement shall be made in writing by the CONTRACTOR within 30 days of when the CONTRACTOR has or should have notice of any actual or claimed change in the work, which results in additional and unanticipated cost to the CONTRACTOR. If the COUNTY Purchasing Agent decides that the facts provide sufficient justification, he may authorize additional payment to the CONTRACTOR pursuant to the claim. Nothing in this section shall excuse the CONTRACTOR from proceeding with performance of the Agreement even if there has been a change.

5. Termination

5.1 COUNTY may, upon fifteen(15) days written notice terminate this Agreement for CONTRACTOR's material breach and if CONTRACTOR does not immediately cure such failure.

5.2 After receipt of the notice of termination, CONTRACTOR shall:

(a) Stop all work under this Agreement on the date specified in the notice of termination.

5.3 After termination, as set out in section 5.1, COUNTY shall make payment only for CONTRACTOR's performance up to the date of termination in accordance with this Agreement.

5.4 CONTRACTOR's rights under this Agreement shall terminate (except for fees accrued prior to the date of termination) upon dishonesty or a willful or material breach of this Agreement by CONTRACTOR; or in the event of CONTRACTOR's unwillingness or inability for any reason whatsoever to perform the terms of this Agreement. In such event, CONTRACTOR shall not be entitled to any further compensation under this Agreement.

5.5 If the Agreement is federally or State funded, CONTRACTOR cannot be debarred from the System for Award Management (SAM). CONTRACTOR must notify the COUNTY promptly of a debarment. Reference: System for Award Management (SAM) at https://www.sam.gov for Central Contractor Registry (CCR), Federal Agency Registration (Fedreg), Online Representations and Certifications Application, and Excluded Parties List System (EPLS)). Excluded Parties Listing System (EPLS) (http://www.epls.gov) (Executive Order 12549, 7 CFR Part 3017, 45 CFR Part 76, and 44 CFR Part 17). The System for Award Management (SAM) is the Official U.S. Government system that consolidated the capabilities of CCR/FedReg, ORCA, and EPLS.

5.6 The rights and remedies of COUNTY provided in this section shall not be exclusive and are in addition to any other rights and remedies provided by law or this Agreement.

6. Intentionally Left Blank

7. Conduct of Contractor

7.1 The CONTRACTOR covenants that it presently has no interest, including, but not limited to, other projects or contracts, and shall not acquire any such interest, direct or indirect, which would conflict in any manner or degree with CONTRACTOR's performance under this Agreement. The CONTRACTOR further covenants that no person or subcontractor having any such interest shall be employed or retained by CONTRACTOR under this Agreement. The CONTRACTOR agrees to inform the COUNTY of all the CONTRACTOR's interests, if any, which are or may be perceived as incompatible with the COUNTY's interests.

7.2 The CONTRACTOR shall not, under circumstances which could be interpreted as an attempt to influence the recipient in the conduct of his/her duties, accept any gratuity or special favor from

individuals or firms with whom the CONTRACTOR is doing business or proposing to do business, in accomplishing the work under this Agreement.

7.3 The CONTRACTOR or its employees shall not offer gifts, gratuity, favors, and entertainment directly or indirectly to COUNTY employees.

8. Intentionally Deleted

8.2 CONTRACTOR shall establish adequate procedures for self-monitoring and quality control and assurance to ensure proper performance under this Agreement.

9. Independent Contractor/Employment Eligibility

9.1 The CONTRACTOR is, for purposes relating to this Agreement, an independent contractor and shall not be deemed an employee of the COUNTY. It is expressly understood and agreed that the CONTRACTOR (including its employees, agents, and subcontractors) shall in no event be entitled to any benefits to which COUNTY employees are entitled, including but not limited to overtime, any retirement benefits, worker's compensation benefits, and injury leave or other leave benefits. There shall be no employer-employee relationship between the parties; and CONTRACTOR shall hold COUNTY harmless from any and all claims that may be made against COUNTY based upon any contention by a third party that an employer-employee relationship exists by reason of this Agreement. It is further understood and agreed by the parties that CONTRACTOR in the performance of this Agreement is subject to the control or direction of COUNTY merely as to the results to be accomplished and not as to the means and methods for accomplishing the results.

9.2 CONTRACTOR warrants that it shall make its best effort to fully comply with all applicable federal and state statutes and regulations regarding the employment of aliens and others and to ensure that employees performing work under this Agreement meet the citizenship or alien status requirement set forth in applicable federal statutes and regulations. Where applicable, CONTRACTOR shall obtain, from all employees performing work hereunder, all verification and other documentation of employment eligibility status required by federal or state statutes and regulations including, but not limited to, the Immigration Reform and Control Act of 1986, 8 U.S.C. §1324 et seq., as they currently exist and as they may be hereafter amended (if applicable, depending on the location of work). CONTRACTOR shall retain all such documentation for all covered employees, for the period prescribed by the law.

9.3 Ineligible Person shall be any individual or entity who: Is currently excluded, suspended, debarred or otherwise ineligible to participate in the federal health care programs; or has been convicted of a

criminal offense related to the provision of health care items or services and has not been reinstated in the federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

9.4 CONTRACTOR shall screen prospective employees, agents, and subcontractors ("Covered Individuals") prior to hire or engagement for performance of work under this agreement. CONTRACTOR shall not hire or engage any Ineligible Person to provide services directly relative to this Agreement. CONTRACTOR shall screen all current Covered Individuals providing services to County within sixty (60) days of execution of this Agreement to ensure that they have not become Ineligible Persons unless CONTRACTOR has performed such screening on same Covered Individuals within the past six (6) months. Covered Individuals shall be required to disclose to CONTRACTOR immediately any debarment, exclusion or other event that makes them an Ineligible Person. CONTRACTOR shall notify COUNTY within five (5) business days after it becomes aware if a Covered Individual providing services directly relative to this Agreement becomes debarred, excluded or otherwise becomes an Ineligible Person.

9.5 CONTRACTOR acknowledges that Ineligible Persons are precluded from providing federal and state funded health care services by contract with COUNTY in the event that they are currently sanctioned or excluded by a federal or state law enforcement regulatory or licensing agency. If CONTRACTOR becomes aware that a Covered Individual has become an Ineligible Person, CONTRACTOR shall remove such individual from responsibility for, or involvement with, COUNTY business operations related to this Agreement.

9.6 CONTRACTOR shall notify COUNTY within five (5) business days if a Covered Individual or entity is currently excluded, suspended or debarred, or is identified as such after being sanction screened. Such individual or entity shall be promptly removed from participating in any activity associated with this Agreement.

10. Subcontract for Work or Services

CONTRACTOR may enter into contracts with third parties to furnish the work or services under this Agreement, provided that (i) CONTRACTOR maintains the ultimate responsibility for fulfilling the terms and conditions of this Agreement to the COUNTY and (ii) CONTRACTOR remains directly responsible to the COUNTY for its subcontractors including subcontractor compliance with this Agreement. At COUNTY's request, CONTRACTOR shall provide the names of each subcontractor that will perform any work or services under this Agreement.

11. Disputes

11.1 The parties shall attempt to resolve any disputes amicably at the working level. If that is not successful, the dispute shall be referred to the senior management of the parties. Any dispute relating to this Agreement, which is not resolved by the parties, shall be decided by the COUNTY's Purchasing Department's Compliance Contract Officer who shall furnish the decision in writing. The decision of the COUNTY's Compliance Contract Officer shall be final and conclusive unless determined by a court of competent jurisdiction to have been fraudulent, capricious, arbitrary, or so grossly erroneous to imply bad faith. The CONTRACTOR shall proceed diligently with the performance of this Agreement pending the resolution of a dispute.

11.2 Prior to the filing of any legal action related to this Agreement, the parties shall be obligated to attend a mediation session in Riverside County before a neutral third party mediator. A second mediation session shall be required if the first session is not successful. The parties shall share the cost of the mediations.

12.

Licensing and Permits

12.1 CONTRACTOR shall comply with all State or other licensing requirements, including but not limited to the provisions of Chapter 9 of Division 3 of the Business and Professions Code. All licensing requirements shall be met at the time proposals are submitted to the COUNTY. CONTRACTOR warrants that it has all necessary permits, approvals, certificates, waivers and exemptions necessary for performance of this Agreement as required by the laws and regulations of the United States, the State of California, the County of Riverside and all other governmental agencies with jurisdiction, and shall maintain these throughout the term of this Agreement.

13. Intentionally Left Blank

14. Non-Discrimination

14.1 CONTRACTOR shall not be discriminate in the provision of services, allocation of benefits, accommodation in facilities, or employment of personnel on the basis of ethnic group identification, race, religious creed, color, national origin, ancestry, physical handicap, medical condition, marital status or sex in the performance of this Agreement; and, to the extent they shall be found to be applicable hereto, shall comply with the provisions of the California Fair Employment and Housing Act (Gov. Code 12900 et. seq), the Federal Civil Rights Act of 1964 (P.L. 88-352), the Americans with Disabilities Act of 1990 (42 U.S.C. S1210 et seq.) and all other applicable laws or regulations.

15. Intentionally Deleted.

16. Confidentiality

16.1 The CONTRACTOR shall not use for personal gain or make other improper use of privileged or confidential information which is acquired in connection with this Agreement. The term "privileged or confidential information" includes but is not limited to: unpublished or sensitive technological or scientific information; medical, personnel, or security records; anticipated material requirements or pricing/purchasing actions; COUNTY information or data which is not subject to public disclosure; COUNTY operational procedures; and knowledge of selection of contractors, subcontractors or suppliers in advance of official announcement.

16.2 The CONTRACTOR shall protect from unauthorized disclosure names and other identifying information concerning persons receiving services pursuant to this Agreement, except for general statistical information not identifying any person. The CONTRACTOR shall not use such information for any purpose other than carrying out the CONTRACTOR's obligations under this Agreement. The CONTRACTOR shall promptly transmit to the COUNTY all third party requests for disclosure of such information. The CONTRACTOR shall not disclose, except as otherwise specifically permitted by this Agreement or authorized in advance in writing by the COUNTY, any such information to anyone other than the COUNTY. For purposes of this paragraph, identity shall include, but not be limited to, name, identifying number, symbol, or other identifying particulars assigned to the individual, such as finger or voice print or a photograph.

16.3 The CONTRACTOR is subject to and shall operate in compliance with all relevant requirements contained in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, enacted August 21, 1996, and the related laws and regulations promulgated subsequent thereto. Please refer to Attachment I of this Agreement.

17. Administration/Contract Liaison

The COUNTY Purchasing Agent, or designee, shall administer this Agreement on behalf of the COUNTY. The Purchasing Department is to serve as the liaison with CONTRACTOR in connection with this Agreement.

18. Notices

All correspondence and notices required or contemplated by this Agreement shall be delivered to the respective parties at the addresses set forth below and are deemed submitted two days after their deposit in the United States mail, postage prepaid:

COUNTY OF RIVERSIDE	**CONTRACTOR**
Riverside University Health System –	**Datix (USA) Inc.**
Medical Center	**311 S. Wacker Drive, Suite 4900**
26520 Cactus Ave.	**Chicago, IL 60606**
Moreno Valley, CA 92555	

19. Force Majeure

If either party is unable to comply with any provision of this Agreement due to causes beyond its reasonable control, and which could not have been reasonably anticipated, such as acts of God, acts of war, civil disorders, strikes or other labor disputes, riots, power grid failure, pandemic, epidemic, hurricanes, earthquakes or other similar acts, such party shall not be held liable for such failure to comply.

20. EDD Reporting Requirements

In order to comply with child support enforcement requirements of the State of California, the COUNTY may be required to submit a Report of Independent Contractor(s) form **DE 542** to the Employment Development Department. The CONTRACTOR agrees to furnish the required data and certifications to the COUNTY within 10 days of notification of award of Agreement when required by the EDD. This data will be transmitted to governmental agencies charged with the establishment and enforcement of child support orders. Failure of the CONTRACTOR to timely submit the data and/or certificates required may result in the contract being awarded to another contractor. In the event a contract has been issued, failure of the CONTRACTOR to comply with all federal and state reporting requirements for child support enforcement or to comply with all lawfully served Wage and Earnings Assignments Orders and Notices of Assignment shall constitute a material breach of Agreement. If CONTRACTOR has any questions concerning this reporting requirement, please call (916) 657-0529. CONTRACTOR should also contact its local Employment Tax Customer Service Office listed in the telephone directory in the State Government section under "Employment Development Department" or access their Internet site at www.edd.ca.gov.

21. Hold Harmless/Indemnification

21.1 CONTRACTOR shall indemnify and hold harmless the County of Riverside, its Agencies, Districts, Special Districts and Departments, their respective directors, officers, Board of Supervisors, elected and appointed officials, employees, agents and representatives (individually and collectively hereinafter referred to as Indemnitees) from any liability, action, claim or damage whatsoever, based or asserted upon any services of CONTRACTOR, its officers, employees, subcontractors, agents or representatives arising out of CONTRACTOR's, its officers', employees', subcontractors', agents', or representatives' (i) negligent acts or omissions while performing under this Agreement that cause property damage, bodily injury, or death and (ii) grossly negligent acts or omissions. CONTRACTOR shall defend the Indemnitees at its sole expense including all costs and fees (including, but not limited, to attorney fees, cost of investigation, defense and settlements or awards) in any such claim or action.

21.2 With respect to any action or claim subject to indemnification herein by CONTRACTOR, CONTRACTOR shall, at their sole cost, have the right to use counsel of their own choice and shall have the right to adjust, settle, or compromise any such action or claim without the prior consent of COUNTY; provided, however, that any such adjustment, settlement or compromise in no manner whatsoever limits or circumscribes CONTRACTOR indemnification to Indemnitees as set forth herein.

21.3 CONTRACTOR'S obligation hereunder shall be satisfied when CONTRACTOR has provided to COUNTY the appropriate form of dismissal relieving COUNTY from any liability for the action or claim involved.

21.4 The specified insurance limits required in this Agreement shall in no way limit or circumscribe CONTRACTOR'S obligations to indemnify and hold harmless the Indemnitees herein from third party claims.

22. Insurance

22.1 Without limiting or diminishing the CONTRACTOR'S obligation to indemnify or hold the COUNTY harmless, CONTRACTOR shall procure and maintain or cause to be maintained, at its sole cost and expense, the following insurance coverage's during the term of this Agreement. As respects to the insurance section only, the COUNTY herein refers to the County of Riverside, its Agencies, Districts, Special Districts, and Departments, their respective directors, officers, Board of Supervisors, employees, elected or appointed officials, agents, or representatives as Additional Insureds.

A. Workers' Compensation:

If the CONTRACTOR has employees as defined by the State of California, the CONTRACTOR shall maintain statutory Workers' Compensation Insurance (Coverage A) as prescribed by the laws of the State of California. Policy shall include Employers' Liability (Coverage B) including Occupational Disease with limits not less than $1,000,000 per person per accident.

B. Commercial General Liability:

Commercial General Liability insurance coverage, including but not limited to, premises liability, contractual liability, products and completed operations liability, personal and advertising injury, and cross liability coverage, covering claims which may arise from or out of CONTRACTOR'S performance of its obligations hereunder. Policy shall name the COUNTY as Additional Insured. Policy's limit of liability shall not be less than $1,000,000 per occurrence combined single limit. If such insurance contains a general aggregate limit, it shall apply separately to this agreement or be no less than two (2) times the occurrence limit.

C. Vehicle Liability:

If vehicles or mobile equipment is used in the performance of the obligations under this Agreement, then CONTRACTOR shall maintain liability insurance for all non-owned, or hired vehicles so used in an amount not less than $1,000,000 per occurrence combined single limit. If such insurance contains a general aggregate limit, it shall apply separately to this agreement or be no less than two (2) times the occurrence limit.

D. Professional Liability Contractor shall maintain Professional Liability Insurance providing coverage for the Contractor's performance of work included within this Agreement, with a limit of liability of not less than $1,000,000 per occurrence and $2,000,000 annual aggregate. If Contractor's Professional Liability Insurance is written on a claims made basis rather than an occurrence basis, such insurance shall continue through the term of this Agreement and CONTRACTOR shall purchase at his sole expense either 1) an Extended Reporting Endorsement (also, known as Tail Coverage); or 2) Prior Dates Coverage from new insurer with a retroactive date back to the date of, or prior to, the inception of this Agreement; or 3) demonstrate through Certificates of Insurance that CONTRACTOR has Maintained continuous coverage with the same or original insurer.

E. Cyber Liability:

CONTRACTOR shall procure and maintain for the duration of this Agreement insurance against claims for injuries to person or damages to property which may arise from or in connection with the

performance of the work hereunder by CONTRACTOR, its agents, representatives, or employees. CONTRACTOR shall procure and maintain for the duration of this Agreement insurance claims arising out of their services and including, but not limited to loss, damage, theft or other misuse of data, infringement of intellectual property, invasion of privacy and breach of data. Cyber liability insurance, with limits not less than $2,000,000 per occurrence or claim, $2,000,000 aggregate. Coverage shall be sufficiently broad to respond to the duties and obligations as is undertaken by CONTRACTOR in this Agreement and shall include, but not limited to, claims involving infringement of intellectual property, including but not limited to infringement of copyright, trademark, trade dress, invasion of privacy violations, information theft, damage to or destruction of electronic information, release of private information, alteration of electronic information, extortion and network security. The policy shall provide coverage for breach response costs as well as regulatory fines and penalties as well as credit monitoring expenses with limits sufficient to respond to these obligations.

If CONTRACTOR maintains broader coverage and/or higher limits than the minimums shown above in Section 22.1, COUNTY requires and shall be entitled to the broader coverage and/or higher limits maintained by CONTRACTOR. Any available insurance proceeds in excess of the specified minimum limits of insurance and coverage shall be available to COUNTY.

F. General Insurance Provisions - All lines:

1) Any insurance carrier providing insurance coverage hereunder shall be licensed in the State of California and have an A M BEST rating of not less than A: VIII (A:8) unless such requirements are waived, in writing, by the County Risk Manager. If the County's Risk Manager waives a requirement for a particular insurer such waiver is only valid for that specific insurer and only for one policy term.

2) The CONTRACTOR must declare its insurance self-insured retention for each coverage required herein. If any such self-insured retention exceeds $500,000 per occurrence each such retention shall have the prior written consent of the County Risk Manager before the commencement of operations under this Agreement. Upon notification of self-insured retention unacceptable to the COUNTY, and at the election of the County's Risk Manager, CONTRACTOR'S carriers shall either; 1) reduce or eliminate such self-insured retention as respects this Agreement with the COUNTY, or 2) procure a bond which guarantees payment of losses and related investigations, claims administration, and defense costs and expenses.

3) CONTRACTOR shall furnish the County of Riverside with either 1) a properly executed Certificate(s) of Insurance and copies of Endorsements effecting coverage as required herein, and 2) if requested to do so orally or in writing by the County Risk Manager, provide copies of policies including all

Endorsements and all attachments thereto, showing such insurance is in full force and effect. CONTRACTOR shall not commence operations until the COUNTY has been furnished Certificate (s) of Insurance and copies of endorsements and if requested, policies of insurance including all endorsements and any and all other attachments as required in this Section. An individual authorized by the insurance carrier shall sign the original endorsements for each policy and the Certificate of Insurance.

4) The insurance requirements contained in this Agreement may be met with a program(s) of self-insurance.

23. General

23.1 CONTRACTOR shall not delegate or assign any interest in this Agreement, whether by operation of law or otherwise, without the prior written consent of COUNTY, except that CONTRACTOR may assign this Agreement to a successor to substantially all of its assets or business. This Agreement shall be binding upon and inure to the benefit of permitted successor of the CONTRACTOR. Any attempt to delegate or assign any interest herein in violation of this section shall be deemed void and of no force or effect.

23.2 Any waiver by COUNTY of any breach of any one or more of the terms of this Agreement shall not be construed to be a waiver of any subsequent or other breach of the same or of any other term of this Agreement. Failure on the part of COUNTY to require exact, full, and complete compliance with any terms of this Agreement shall not be construed as in any manner changing the terms or preventing COUNTY from enforcement of the terms of this Agreement.

23.3 In the event the CONTRACTOR receives payment under this Agreement, which is later disallowed by COUNTY for nonconformance with the terms of the Agreement, the CONTRACTOR shall promptly refund the disallowed amount to the COUNTY on request; or at its option the COUNTY may offset the amount disallowed from any payment due to the CONTRACTOR.

23.4 Each Party shall hold itself to high ethical standards, including basic human rights, not engaging in any activity, practice or conduct which would constitute an offence under anti-slavery or anti-bribery legislation, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner, without corruption.

23.5 CONTRACTOR shall not provide any services or products subject to any chattel mortgage or under a conditional sales contract or other agreement by which an interest is retained by a third party. The

CONTRACTOR warrants that it has good title to all materials or products used by CONTRACTOR or provided to COUNTY pursuant to this Agreement, free from all liens, claims, or encumbrances.

23.6 Nothing in this Agreement shall prohibit the COUNTY from acquiring the same type or equivalent equipment, products, materials or services from other sources, when deemed by the COUNTY to be in its best interest. The COUNTY reserves the right to purchase more or less than the quantities specified in this Agreement.

23.7 The COUNTY agrees to cooperate with the CONTRACTOR in the CONTRACTOR's performance under this Agreement, including, if stated in the Agreement, providing the CONTRACTOR with reasonable facilities and timely access to COUNTY data, information, and personnel.

23.8 CONTRACTOR shall comply with all applicable Federal, State and local laws and regulations. CONTRACTOR will comply with all applicable COUNTY policies and procedures. In the event that there is a conflict between the various laws or regulations that may apply, the CONTRACTOR shall comply with the more restrictive law or regulation.

23.9 CONTRACTOR shall comply with all air pollution control, water pollution, safety and health ordinances, statutes, or regulations, which apply to performance under this Agreement.

23.10 CONTRACTOR shall comply with all applicable requirements of the Occupational Safety and Health Administration (OSHA) standards and codes as set forth by the U.S. Department of Labor and the State of California (Cal/OSHA).

23.11 No Offshore Work or Services Involving PHI: CONTRACTOR shall not transmit PHI outside of the United States of America (USA). Additionally, no CONTRACTOR employees, agents and/or subcontractors outside of the USA will receive, process, transfer, handle, store or have access to PHI in oral, written, or electronic form. COUNTY recognizes that as a result of the foregoing certain service commitments, including service commitments set out in this Agreement, may be impacted. For example, CONTRACTOR's response times may be delayed where offshore resources would otherwise have been involved.

23.12 This Agreement shall be governed by the laws of the State of California. Any legal action related to the performance or interpretation of this Agreement shall be filed only in the Superior Court of the State of California located in Riverside, California, and the parties waive any provision of law providing for a change of venue to another location. In the event any provision in this Agreement is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions will nevertheless continue in full force without being impaired or invalidated in any way.

23.13 This Agreement, including any attachments or exhibits, constitutes the entire Agreement of the parties with respect to its subject matter and supersedes all prior and contemporaneous representations, proposals, discussions and communications, whether oral or in writing. This Agreement may be changed or modified only by a written amendment signed by authorized representatives of both parties.

23.14 Electronic Signatures. This Agreement may be executed in any number of counterparts, each of which will be an original, but all of which together will constitute one instrument. Each party of this Agreement agrees to the use of electronic signatures, such as digital signatures that meet the requirements of the California Uniform Electronic Transactions Act (("CUETA") Cal. Civ. Code §§ 1633.1 to 1633.17), for executing this Agreement. The parties further agree that the electronic signatures of the parties included in this Agreement are intended to authenticate this writing and to have the same force and effect as manual signatures. Electronic signature means an electronic sound, symbol, or process attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the electronic record pursuant to the CUETA as amended from time to time. The CUETA authorizes use of an electronic signature for transactions and contracts among parties in California, including a government agency. Digital signature means an electronic identifier, created by computer, intended by the party using it to have the same force and effect as the use of a manual signature, and shall be reasonably relied upon by the parties. For purposes of this section, a digital signature is a type of "electronic signature" as defined in subdivision (h) of Section 1633.2 of the Civil Code.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Agreement.

COUNTY OF RIVERSIDE, a political subdivision of the State of California

By: _____
Chuck Washington, Chair
Board of Supervisors

Dated: 4/30/2024

ATTEST:
KIMBERLY A. RECTOR
Clerk of the Board

By: _____
Deputy

APPROVED AS TO FORM:
Minh C. Tran
County Counsel

By: _____
Tawny Lieu
Deputy County Counsel

Datix (USA) Inc.

By: John Osment
John Osment (Mar 22, 2024 13:08 GMT)
Name: John Osment
Title: VP Commercial Operations

Dated: 03/22/2024

APR 30 2024 15.2

EXHIBIT A
SCOPE OF SERVICES

This Exhibit A describes the software licenses, products, and services that CONTRACTOR shall provide to COUNTY under this Agreement.

	Subscription License
Hosting Type	Client Hosted
Number of live database limit	Use Existing Database
FTE limit	3,836
The Licensed Material are restricted for use only at the following	**Listed Licensed Locations** 1. RUHS MC 2. RUHS ARLINGTON 3. RUHS BEHAVIORAL HEALTH 4. RUHS MSC 5. RUHS Community Health Clinics 6. RUHS Ambulatory Care Clinics 7. All current locations of Riverside University Health System **Unlisted Licensed Locations** The Licensed Materials may also be used at affiliated locations (which are not specifically identified above) as long as none of the unlisted licensed locations exceeds 100 FTEs and the aggregate total of all unlisted licensed locations does not exceed 400 FTEs. "FTE" refers to full-time equivalent number of employees.

1. Licenses

a. Risk:

• Risk Entry - Unlimited access for Incident reporting/submission for entire organization.

• Risk Enterprise File Managers - Unlimited licenses for organization to manage and investigate incoming Incident files.

• 2 Risk Administrators - Licenses needed for unlimited access to the RL6 Risk module for making changes possible within the module, dedicated to technical teams and resources.

• 5 Risk Basic Administrators - Licenses allowing users to make changes to reports, forms, files, intended for less technical business users.

b. Peer Review

• Peer Review Enterprise File Managers - Unlimited licenses for organization to manage all Peer Review Files.

• 5 Peer Review Basic Administrator - Licenses allowing users to make changes to reports, forms, files, intended for less technical business users.

• 2 Peer Review Administrators - Licenses needed for unlimited access to the RL6 Peer Review module for making changes possible within the module, typically dedicated to technical teams and resources.

c. Claims

• Claims Financial Module - Tool available within Claims management module to document and management financial aspects of claims files within the system.

• 10 Claims File Managers - Licenses dedicated to users accessing and managing claims entries.

• 2 Claims Administrators - Licenses needed for unlimited access to the RL6 Claims module for making all changes possible within the module, typically dedicated to technical teams and resources.

• 5 Claims Basic Administrator - Licenses allowing users to make changes to reports, forms, files, usually intended for less technical business users.

2. Interfaces

• Patient Lookup Interface (HL7) - Interface that searches and pulls patient demographic data into the RL6 platform.

• External Authentication: Federated (SAML) - Authentication method used for seamless user login and access management.

• Report Designer - Create and share customized reports with department heads and leadership to provide context to collected data.

• Forms Designer - Build customized forms and to collect actionable information across all RL6 modules.

• Medication Lookup Import Utility (CSV) -Allow reporters to lookup medications and link directly to submission details. Makes submission easier with rich, actionable data.

3. Services

• One Time Data Extract of Files - Service to extract legacy DatixWeb files for continued searching and retrieval.

• Hosting Services - One time fee to support implementation of the RL6 Hosted environment.

• Implementation Services (up to 178 hours) - One time fee for all RL6 module implementation hours needed to successfully implement and train on RL6.

• Technical Service Hours (up to 15 hours) - One time fee for technical hours needed to complete External Authentication and Medical Lookup integrations.

• Silver Success Plan - Annual fee that includes 50 hours of access to a Success Manager (SM), a system expert who can remotely maintain software and configure COUNTY pick lists, forms, reports, alerts, and more to expand the use of the system. The Success plan is strongly recommended for all customers moving from DatixWeb to RL6 to support beyond implementation, and ensure immediate access to a Success Manager who can make any and all changes in the system for COUNTY if needed, and support a successful platform swap.

EXHIBIT B
PAYMENT PROVISIONS

For software licenses, products, and services provided by CONTRACTOR as described in Exhibit A and in accordance with the terms and conditions of the Agreement, CONTRACTOR shall be entitled to receive payment as set forth below.

Pricing

Year 1	**$ 220,159.00**
Year 2	**$ 164,938.02**
Year 3	**$ 169,886.16**
Year 4	**$ 174,982.75**
Year 5	**$ 180,232.23**
TOTAL	**$ 910,198.16**

Year 1 fees are broken down at follows: Initial setup fee - $60,025, Annual Subscription Fee - $149,134 and $11,000 Success Plan

Exhibit C – Software Licensing Terms

County of Riverside (defined as Client) and Datix (USA) Inc. (defined as RLDatix) (each individually is a "Party" and together they are the "Parties") hereby agree as follows:

1. SCOPE

1.1. The terms and conditions of this Exhibit C apply to Client's use of the RLDatix's products or services under this Agreement. The Parties acknowledge that in entering into this Agreement they have not relied upon any representations other than those reduced to writing in this Agreement.

1.2. **Purchase Order ("PO") Requirements**: Client expressly agrees that terms and conditions provided und any PO provided to RLDatix shall be of no force and effect and shall be excluded from any Agreement. Client will provide any required POs promptly on signing of this Agreement.

2. DEFINITIONS

2.1. "Authorized Users" shall consist of the individuals Client permits to either access or use the Licensed Materials and is a subset of the individuals included in Client's FTE number as indicated in Exhibit A.

2.2. "Confidential Information" means all confidential information disclosed by a Party (the "Disclosing Party") to the other Party (the "Receiving Party") whether orally or in writing, that is designated as confidential or that reasonably should be understood to be confidential given the nature of the information and the circumstances of the disclosure, and includes this business and marketing plans, technology and technical information, product plans and designs and business processes disclosed by such Party. Notwithstanding the foregoing, Confidential Information does not include any information that (i) is or becomes generally known to the public without breach of any obligation owed to the Disclosing Party, (ii) was known to the Receiving Party prior to its disclosure by the Disclosing Party without breach of any obligation owed to the Disclosing Party, (iii) is received from a third party without breach of any obligation owed to the Disclosing Party, or (iv) was independently developed by the Receiving Party, as demonstrated by Receiving Party's written records. Where the Disclosing Party is the Client, Confidential Information shall not include any information provided by Client through public forums or de-identified or aggregated data, provided that such data is de-identified in compliance with HIPAA requirements as set forth in 45 CFR § 164.514(a)-(c).

2.3. "Client Data" means all electronic data or information submitted by Client to be stored or processed in the Licensed Materials.

2.4. "Documentation" means the published user manuals and other written materials concerning the Licensed Materials that RLDatix generally makes available to its clients from time to time.

2.5. "Enhancements" means any updates, upgrades, improvements or new versions of the Software or Documentation that RLDatix may release or make generally available to its clients from time to time, which items are also subject to license.

2.6. "FTE" means full time equivalents. FTEs are expressed in numerical units, with full time workers expressed as 1.0 FTE and half-time workers expressed as 0.5 FTE. As used in connection with this Agreement, Client's FTEs include: (i) all of Client's employees, (ii) Client's agents and affiliates, (iii) Permitted Independent IT Contractors, (iv) independent or contract medical personnel (physicians, nurses, pharmacists, etc.) including their support and ancillary staff, and (v) any other groups of health

care providers, medical workers and volunteers having privileges or working with Client. Client's FTEs are deemed to exclude: Client's patients and customers (to the extent that they do not fall into one of the other groups of individuals listed in the preceding sentence).

2.7. "IP Claim" means any claim, suit or proceeding filed against Client by any third party to the extent that such claim, suit or proceeding asserts that the Licensed Materials infringe any intellectual property rights of such third party in Canada, the United States, the United Kingdom, Australia or the EU.

2.8. "Licensed Materials" means (i) the Software, (ii) the Documentation, (iii) any Enhancements; (iv) any Modifications; (v) any Professional Services and (vi) any copy of the Software, Documentation, Enhancements or Modifications and Third Party Software.

2.9. "Licensed Thresholds" refers to the limitations on use specified on the Order such as, without limitation, the following: license type (i.e. the functionality included in the license to Client); number of licensed users (meaning the absolute number of permitted users of the Software rather than the FTE count); number of different types of users; Listed Licensed Locations and Unlisted Licensed Locations; and the FTE limit.

2.10. "Listed Licensed Locations", "Unlisted Licensed Locations" and "Non-Licensed Locations" are as indicated on the Order: Listed Licensed Locations being specified by name. All authorized locations must be listed and may be excluded from the list only in accordance with terms for locations on the Order. A Non-Licensed Location is a location that does not include the Listed Licensed Locations and/or the Unlisted Licensed Locations as set forth in Exhibit A.

2.11. "Minimum Commitment" means a minimum term of Maintenance and/or a subscription as specified on the Order.

2.12. "Modifications" means any alteration, change or modification to any Licensed Materials made at Client's request.

2.13. "Order" refers to the order form or quotation provided by RLDatix to Client that specifies the fees and certain parameters for the Licensed Materials, such as, without limitation, License Thresholds. For clarity, the first Order is Exhibit A and Exhibit B read together.

2.14. "Permitted Independent IT Contractor" means an individual or group of individuals not employed by Client but who are engaged in work that supports Client's use of the Licensed Materials. To qualify as Permitted Independent IT Contractors, such individuals or group of individuals must be identified on the Order, must be included in the FTE count, and must not provide services to, or on behalf of, any business which is competitive with RLDatix.

2.15. "Software" means the RLDatix-owned computer programs identified on the Order, together with any Enhancements or Modifications.

2.16. "Standard Support Plan" means the RLDatix Standard Support Plan, the most current copy of which is always available at https://www.rldatix.com/en-nam/msa. Exhibit D contains the version of the Standard Support Plan that was in existence at the time of signing the Agreement, for references purposes.

2.17. "Third Party Software" means any computer programs not owned by RLDatix that are licensed to Client and provided along with the Licensed Materials.

2.18. "Taxes" means any taxes, levies, duties or similar governmental assessments of any nature, including but not limited to value-added, sales and use, or withholding taxes, assessable by any local, state, provincial, federal or foreign jurisdiction.

3. LICENSED MATERIALS

3.1. **Right to Use Licensed Materials**: **License Grant**. RLDatix hereby grants to Client a non-transferable, non-exclusive subscription license for its Authorized Users to remotely access and use the Licensed Material, subject to the License Threshold limitations set forth in this Agreement and the associated Order (including the duration of any Subscription License or renewal thereof) up to the FTE threshold for which the Fee has been paid, solely at the Listed Licensed Location(s) and Unlisted Licensed Locations as specified and defined on the Order (as modified by the process in section 3.6), and provided always that the FTE and live database limits specified and defined on the Order are not exceeded (the "**License**"). Client shall ensure that the Licensed Materials are not used at Non-Licensed Locations.

3.2. **Limitations**. Any right not specifically granted herein is reserved. Client shall have no right to assign, sublicense, transfer, rent, lease, or distribute the Licensed Materials. No right of ownership or any other exclusive right in any particular manner of configuration, customization or setup of the Licensed Materials performed by RLDatix is granted to Client. No right is granted to the Client to use the Licensed Materials other than in support of Client's own internal business processes and activities. No right is granted to the Client herein to operate the Licensed Materials in a service bureau, outsourcing business or other manner in which the Licensed Materials are used to process or manage information other than that generated by Client in the course of Client's own internal operations. Subject to this section, Client specifically agrees to refrain from any direct or indirect efforts or attempts to reverse engineer, decompile, or disassemble the Licensed Materials or to develop any derivative work thereof of any kind. Client shall not remove or obscure any proprietary notices or labels on the Licensed Materials or infect the Licensed Materials with viruses or any other computer code, files or programs that interrupt, destroy, or limit their functionality. Client shall permit only Authorized Users to access the Licensed Materials and only for the exclusive purpose of operating the Licensed Materials in the course of Client's business. Client shall ensure that each Authorized User has, and only uses his or her own, unique account name and password combination to access the Software. Client shall not permit more than one person to use any one account name and password combination. Client shall not permit any person or entity other than RLDatix to maintain or in any way change or modify the Licensed Materials or any element thereof. If Client has elected for a Subscription License, Client's right to the use of the Licensed Materials is limited to the duration of the Subscription License (or any renewal thereof) for which the Subscription License fee has been paid.

3.3. **Warranty**. RLDatix warrants that it has the right to (i) enter into this Agreement; (ii) grant the licenses offered pursuant this Agreement; and (iii) grant the right for Client and its Authorized Users to make use of the Third-Party Software.

3.4. **Limited Warranty**. RLDatix warrants that Software will be free, at the time of delivery, of harmful code (i.e., computer viruses, worms, trap doors, time bombs, disabling code, or similar malicious mechanism designed to interfere with the intended operation of, or cause damage to, data, or instruments). No warranty or assurance is made as to the ability of the Software to satisfy any or all of Client's particular requirements or that use of the Software will be uninterrupted or error free. Any warranties set forth in this Agreement shall not apply to the extent that (i) the Software is not used in accordance with the then-current Documentation, (ii) Client makes any changes to the underlying

Software that have not been approved in writing by RLDatix, and/or (iii) the nonconformity is due to the misuse of the Software.

3.5. **Authorized Users**. Only Authorized Users are entitled to make use of and access the Licensed Materials, and only then (i) from Listed Licensed Locations and/or Unlisted Licensed Locations as specified and defined on the Order, using a secure connection to the server hosting the Software for Client and (ii) exclusively to operate the Software for Client's internal business. As such, Client will ensure that only Authorized Users have access to the Licensed Materials.

3.6. **Location Substitution and FTE Limit**. Client may substitute one permitted location for another Listed License Location, provided that (i) the new location replaces either an original location on the initial Order or a location subsequently added via this process, (ii) the new location is in the same country as the location it is replacing, (iii) the FTE number of the new location is the same or smaller than the FTE number at the replaced location, and (iv) Client provides RLDatix with written notice of the change within 90 days of making the substitution (and Client must include in such notice the address and FTE total of both the new and replaced location(s)), and (iv) the Licensed Materials are no longer used at the replaced location. Supplemental License Fees will be applicable where FTE growth and/or new locations (in relation to the Order), cannot be accommodated through the process of Location Substitution per this paragraph.

3.7. **Acceptance**. Within three (3) months of delivery of the Licensed Materials or making them available for use or download, Client shall complete testing and evaluation of the Licensed Materials. In the event that there is a material non-conformance in the operation of the Software or a material non-conformance in the other Licensed Materials during this period, Client shall provide written notice thereof to RLDatix. A material non-conformance in the operation of the Software is defined as a Severity Level 1 or Severity Level 2 issue as per the Standard Support Plan. RLDatix shall then have fourteen (14) days to address the non-conformance or defect in accordance with the terms of the Standard Support Plan and to provide Client with a written Notice of Repair, thereafter starting a fourteen (14) day time period for Client to retest and re-evaluate the Licensed Materials. In the event the non-conformance is not cured within this time period, Client, at its sole discretion, can extend the cure period for such non-conformances or terminate the applicable Order. The Licensed Materials shall be deemed accepted by Client upon the earliest of (i) Client providing written notice of acceptance, (ii) Client not presenting a notice of non-conformance or defect within the first thirty (30) days after Client places the Software into a production/live environment for go live, (iii) Client not presenting a notice of non-conformance or defect within the first three (3) months after the Licensed Materials is made available to Client for use (or, as the case may be within three (3) months of making the Licensed Materials available for download), or (iv) more than fourteen (14) days passing since RLDatix's last Notice of Repair being provided to Client without a written notice of material non-conformity being issued by Client, such date being the "Acceptance Date".

3.8. **Professional Services**: RLDatix will provide any required implementation and professional services as listed in the Order (the "Professional Services") and defined in an applicable Statement of Work ("SOW").

3.9. **Data Protection:** RLDatix will maintain appropriate administrative, physical and technical safeguards designed for the protection of the security, confidentiality and integrity of Client Data, including measures designed to prevent access, use, modification or disclosure of Client Data by RLDatix personnel, as required to provide the Licensed Materials and prevent or address service or technical problems.

3.10. **Support and Maintenance**. Support and maintenance services ("Maintenance") will be provided in accordance with the then-current version of the Standard Support Plan. RLDatix reserves the right to make changes to the Standard Support Plan and the policies within it to improve or enhance the support and maintenance. If any changes are made, RLDatix will provide at least sixty (60) days prior written notice to Client.

3.11. **Limitation on Version**. RLDatix will provide Maintenance for only the most current version of the Software and the previous two versions preceding the release of the most current version of the Software, subject only to Client's payment of the applicable Maintenance fees as provided hereunder. RLDatix may, in its sole discretion, offer Maintenance on a time and materials basis for older versions of the Software and shall be predicated on Client currently receiving Maintenance.

3.12. **Professional Services Terms and Conditions**. The parties agree that all Professional Services will be supplied in accordance with the relevant Order and any associated SOW. If Client does not materially adhere to the guidelines in the relevant SOW, RLDatix reserves the right to either (i) perform the services on a time and materials basis, or (ii) not perform the services. Services dates and times which have been agreed to by both parties which are later cancelled or rescheduled at Client's request will require that: (i) all such fees for delivered Professional Services shall become due and payable within thirty (30) days; (ii) Client shall reimburse RLDatix for expenses incurred prior to the cancellation or rescheduling notice being received; and (iii) if RLDatix is notified less than twenty (20) business days before the scheduled date, forfeiture by Client of the service hours which RLDatix is reasonably unable to re-book with another client for the same date and time. Any Services listed on the associated Order must be used by Client prior to the one-year anniversary of the Effective Date. Any Services unused by Client as of that time shall expire. Unused services cannot be transferred to other engagements.

4. CLIENT RESPONSIBILITIES WITH RESPECT TO THE LICENSED MATERIALS

4.1. **Responsibilities**: Client shall ensure that: (i) the maximum number and type of Authorized Users that will be permitted to use the Licensed Materials and their mode of access shall comply with the applicable Order; (ii) the Authorized Users will use the Licensed Materials in accordance with the terms and conditions of this Agreement and the applicable Order; and (iii) its network and systems used in conjunction with the Licensed Materials comply with the Documentation that may be updated from time to time. Client is solely responsible for procuring and maintaining its network connections and telecommunications links from its systems to RLDatix's data centers and maintaining the security of its equipment and account access passwords. Client shall cooperate with RLDatix to permit RLDatix to install, support, troubleshoot or otherwise provide services, which may include but not be limited to the provision of reasonable facilities and access to systems and equipment and the

assignment of appropriately skilled and trained personnel to interact with RLDatix representatives. If Client fails to fulfill its responsibilities, RLDatix shall be relieved of the obligation to provide services to Client which are made more difficult or expensive by reason of Client's failure to fulfill Client's responsibilities. RLDatix may, in its sole discretion, offer to continue providing services to Client under such circumstances for an additional charge.

4.2. **Client Data:** Client acknowledges that the collection of Client Data is the sole and exclusive responsibility of Client. Client acknowledges that RLDatix is not responsible in any way for any intellectual property infringement or the violation of any third party's rights or any laws, including but not limited to infringement or misappropriation of copyright, trademark or other property right of any person or entity, arising from or relating to the Client Data. In relation to all personal data comprised within the Client Data, Client warrants that such personal data shall have been obtained and supplied to RLDatix in compliance with applicable laws and Client warrants that it has obtained all necessary consents and approvals from users that are necessary to permit RLDatix to provide the services under this Agreement. Client further agrees to not use the Licensed Materials to store, process or transmit any sensitive financial information, including but not limited to any account number, credit or debit card number (with or without any required security code) or password that would permit access to an individual's financial account, and RLDatix disclaims responsibility for any such data.

4.3. **Trade Sanctions:** Each party will comply with all applicable import, re-import, sanctions, anti-boycott, export, and re-export control laws and regulations. For clarity, the Client is solely responsible for compliance related to the manner in which the Client chooses to use the Licensed Materials, including the Client's transfer and processing of Client Data. The Client represents and warrants that the Client is not subject to sanctions or otherwise designated on the U.S. Government's list of prohibited or restricted parties.

5. Intentionally Left Blank

6. PROPRIETARY RIGHTS

6.1. **Licensed Materials**: Subject to the limited rights expressly granted hereunder, RLDatix reserves all rights, title and interest in and to the Licensed Materials and all modifications and improvements to the Licensed Materials, plus all related intellectual property rights. Except as expressly stated in this Agreement, this Agreement does not grant Client any rights to, or in, patents, copyrights, database rights, trade secrets, trade names, trademarks (whether registered or unregistered), or any other rights or licenses in respect of the Licensed Materials. Any Modifications to any part of the Licensed Materials, excluding the Third Party Software, will be owned by RLDatix immediately on creation regardless of whether the Modifications were made at the request of Client or not. To the extent that Client owns or acquires any right, title, or interest in and to any Modifications, Client hereby assigns RLDatix all such right, title, and interest in and to such Modifications, including all intellectual property rights therein. RLDatix will own all intellectual property rights in any works created in performing this Agreement or in providing any Licensed Materials or Professional Services.

6.2. **Client Data**: Client reserves all rights, title and interest in and to the Client Data, and subject to the limited rights granted by Client hereunder, RLDatix acquires no right, title or interest from Client under this Agreement in or to Client Data or any intellectual property rights therein. Client hereby grants to RLDatix an irrevocable, non-exclusive, royalty-free, worldwide, perpetual license to (i) de-identify any and all Protected Health Information obtained by RLDatix under this Agreement in accordance with the de-identification requirements of 45 CFR 164.514(a)-(b), and use and disclose

such de-identified data consistent with 45 CFR 164.502(d) for the proper management and administration of RLDatix or to carry out its legal responsibilities, and (ii) combine Protected Health Information disclosed by Client to RLDatix with any de-identified or aggregated data maintained by RLDatix (provided that aggregated Protected Health Information is first de-identified by RLDatix in accordance with HIPAA), and to make such Protected Health Information available to other Covered Entities (as defined under HIPAA) to enable such Covered Entities or RLDatix to perform comparative analyses of their healthcare operations with the benefit of such data.

6.3. **Audit Rights.** Client shall maintain accurate books and records relating to the Licensed Materials, including but not limited to the use made thereof by Client in comparison to the License Thresholds and limitations on the Order. Wherever possible, such books and records shall be in a form to permit remote access and review. RLDatix may, at its sole cost and expense, conduct an audit of Client's books and records relating to the Licensed Materials during normal business hours, with reasonable advanced notice and no more frequently than annually, and subject to any reasonable requirements of Client in respect of confidentiality. In the event that an audit reveals that Client's use of the Licensed Materials is in excess of any License Thresholds at any time, Client shall immediately tender the applicable supplemental fees, and should the audit reveal that Client's use was more than 5% in excess of any License Threshold at any time, Client shall reimburse RLDatix for the reasonable costs of the audit.

6.4. **Third Party Applications:** Third-Party applications purchased by Client through RLDatix or otherwise shall not be governed by this Agreement. Some elements of Third-Party Software require the distribution of separate notices, license terms and/or source code, and all Third-Party Software is subject to the license terms of such Third Party Software. None of the terms of the Third-Party Software licenses diminish or minimize the rights RLDatix is otherwise offering to Client in this Agreement. For each such element of Third-Party Software, the applicable licenses, notices or other elements can be found on the distribution media for the Software licensed by this Agreement in the folder named "Third-Party Software" and on the RLDatix web site at https://rldatix.com/en-nam/company/terms.

7. CONFIDENTIALITY

7.1. **Confidentiality**: The Receiving Party shall: (i) protect the Disclosing Party's Confidential Information using the same degree of care that it uses to protect the confidentiality of its own Confidential Information of like kind (but in no event less than reasonable care); (ii) not use (except to perform its obligations hereunder or exercise its rights hereunder) or disclose to any third person any such Confidential Information, and (iii) except as otherwise authorized by the Disclosing Party in writing, limit access to such Confidential Information to those of its employees, contractors and agents who need such access for purposes consistent with this Agreement and who have signed confidentiality agreements with the Receiving Party containing protections no less than those herein. If the Receiving Party is required by law to make any disclosure of such Confidential Information, the Receiving Party, if permitted by law, shall first give written notice of such requirement to the Disclosing Party, and shall permit the Disclosing Party to intervene in any relevant proceedings to protect its interests in the Confidential Information, and reasonably cooperate with the Disclosing Party in seeking to obtain such protection. RLDatix may also disclose the terms and conditions of this Agreement to actual or potential financing sources or acquirers.

7.2. **Feedback**: To the extent Client provides any suggestion, idea, enhancement requests, recommendations or comments ("Feedback") to RLDatix, such Feedback will not be considered Confidential Information and RLDatix will have the unrestricted right to use, profit from, disclose,

publish or otherwise exploit any Feedback without any compensation to Client. Client shall have no intellectual property rights in any developments arising from any Feedback.

7.3. RLDatix acknowledges that the Client is a governmental entity subject to the California Public Records Act (Government Code section 7920.000 et seq.) and the California Ralph M. Brown Act (Government Code section 54950 et seq.). Section 7.1 shall not apply with respect to Client's disclosures of RLDatix's Confident Information pursuant to such statutes. Further, this Agreement (including all attachments and exhibits) is not Confidential Information and is subject to disclosure by Client pursuant to the foregoing statutes.

8. DISCLAIMER

8.1. EXCEPT FOR THE EXPRESS WARRANTIES SET OUT IN EACH SCHEDULE, RLDATIX MAKES NO OTHER WARRANTIES, REPRESENTATIONS OR CONDITIONS, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION THAT OPERATION AND ACCESS OF THE LICENSED MATERIALS WILL BE UNINTERRUPTED OR ERROR FREE, OR ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE OR SATISFACTORY QUALITY OR THOSE ARISING FROM STATUTE OR USAGE OF TRADE.

8.2. CLIENT ACKNOWLEDGES AND AGREES THAT RLDATIX HAS NOT REPRESENTED ITS PRODUCTS AS HAVING THE ABILITY TO DIAGNOSE DISEASE, PRESCRIBE TREATMENT, OR PERFORM ANY OTHER TASKS THAT CONSTITUTE THE PRACTICE OF MEDICINE. THE PARTIES AGREE THAT, AS BETWEEN CLIENT AND RLDATIX, CLIENT IS RESPONSIBLE FOR THE ACCURACY AND QUALITY OF CLIENT CONTENT AS INPUT INTO THE PRODUCTS. CLIENT ACKNOWLEDGES AND AGREES THAT RLDATIX DOES NOT PROVIDE MEDICAL SERVICES TO PATIENTS AND THAT THE OBLIGATION TO EXERCISE INDEPENDENT MEDICAL JUDGMENT IN RENDERING HEALTH CARE SERVICES TO PATIENTS LIES SOLELY WITH THE HEALTHCARE PROFESSIONAL PROVIDING THE SERVICES.

9. INDEMNIFICATION FOR INTELLECTUAL PROPERTY INFRINGEMENT

9.1. RLDatix will defend at its expense any IP Claim and will pay all costs and damages finally awarded against Client by a court of competent jurisdiction or any settlement amounts finally agreed to by RLDatix as a result of any such IP Claim, provided that Client (i) promptly notifies RLDatix in writing of such IP Claim, (ii) transfers sole control of the defense of the IP Claim and all negotiations leading to a settlement or resolution (provided that Client will have the right to reasonably participate, at its own expense, in the defense of any such IP Claim); and (iii) fully cooperates with and assists RLDatix in the defense of such IP Claim.

9.2. If an IP Claim arises, or in RLDatix's opinion, may arise, then RLDatix may at its sole option and in its sole discretion (i) replace or modify that portion of the Licensed Materials so as to avoid the IP Claim; (ii) procure the right for Client to continue the use of the Licensed Materials, or (iii) terminate that portion of the applicable Order corresponding to the IP Claim and refund to Client a pro rata amount of the fees actually paid by Client to RLDatix for the unused portion of the annual fees for such Order.

9.3. The foregoing indemnities will not apply to any IP Claim based upon or arising from (i) any unauthorized use or modification of the Licensed Materials; (ii) use of the Licensed Materials in combination with any software, data, content or hardware not provided or required by RLDatix, to the extent the IP Claim relates to the combination or (iii) any work product based on specifications provided by Client to the extent the IP Claim related to such work product created based on those specifications.

9.4. THE FOREGOING REPRESENTS CLIENT'S SOLE AND EXCLUSIVE REMEDY AND RLDATIX'S ENTIRE LIABILITY AND OBLIGATION WITH RESPECT TO ANY ACTUAL OR ALLEGED INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHT.

10. LIMITATION OF LIABILITY

10.1. TO THE EXTENT ALLOWED BY LAW, IN NO EVENT SHALL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR PUNITIVE DAMAGES HOWEVER CAUSED, INCLUDING LOSS OF DATA, LOSS OF PROFIT, LOSS OF REVENUES OR OTHER COMMERCIAL OR ECONOMIC LOSS, WHETHER IN CONTRACT, TORT OR UNDER ANY OTHER THEORY OF LIABILITY, AND WHETHER OR NOT THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10.2. IN NO EVENT SHALL EITHER PARTY'S TOTAL LIABILITY ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER IN CONTRACT OR TORT OR UNDER ANY OTHER THEORY OF LIABILITY, EXCEED FIVE TIMES THE AMOUNT PAID BY CLIENT IN THE TWELVE MONTHS PRECEDING THE DATE OF THE CLAIM LEADING TO SUCH LIABILITY.

10.3. SECTION 10.2 SHALL NOT APPLY TO (i) CLIENT'S PAYMENT OBLIGATIONS FOR THE SERVICES UNDER THIS AGREEMENT; (ii) ANY BREACH OF SECTION 4.1; (iii) INDEMNIFICATION OBLIGATIONS UNDER SECTION 9.1 OF THIS EXHIBIT C,SECTION 21 OF THE UNDERLYING AGREEMENT; OR (iv) EITHER PARTY'S FRAUD, WILFUL MISCONDUCT OR GROSS NEGLIGENCE.

11. Hosted Platform Terms

11.1 SERVICE - RLDatix will provide the RLDatix Platform and related support services (in accordance with the Standard Support Plan). Client's Subscription License Fee includes a non-cancellable subscription to Maintenance for the term of the Subscription License or any renewal thereof.

11.2 Warranty

(i) Hosting Warranty: RLDatix warrants that the Software, as delivered, shall perform materially in accordance with the specifications contained in the then current Documentation that relates to the Software. In the event of any breach of the warranty in this sub-section during the term of this Agreement, RLDatix shall, as its sole liability and Client's sole remedy (in addition to any termination right that may arise from such warranty breach), diligently remedy such deficiencies that cause Software to not conform to this warranty. If RLDatix determines that it is unable to remedy such deficiencies, RLDatix may terminate that portion of the applicable Order affected and refund to Client a pro rata amount of the fees actually paid by the Client to RLDatix for the unused Subscription Term of the defective Software.

(ii) Professional Services Warranty: RLDatix warrants that the Professional Services will be performed in a professional and workmanlike manner consistent with applicable industry standards. Client's sole and exclusive remedy (in addition to any termination right that may arise from such warranty breach) with respect to this warranty will be that RLDatix shall correct the breach of this warranty or reperform the services within a commercially reasonably period of time, provided that Client reports any warranty claims to RLDatix within thirty (30) days of the delivery of the related Professional Services.

(iii) EXCEPT FOR THE EXPRESS WARRANTIES SET OUT ABOVE, RLDATIX MAKES NO OTHER WARRANTIES, REPRESENTATIONS OR CONDITIONS, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION THAT OPERATION AND ACCESS OF THE SERVICES WILL BE UNINTERRUPTED OR ERROR FREE, OR ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE OR SATISFACTORY QUALITY OR THOSE ARISING FROM STATUTE OR USAGE OF TRADE.

11.3 Return of Client Data: Upon Client's written request, where such request must be made within sixty (60) days following expiration or termination of this Agreement, RLDatix shall return or, if agreed to in writing by Client, destroy Client Data. When returning Client Data, RLDatix shall return to Client via secure FTP and in an industry standard file format at no cost to Client. All Client Data shall be deleted by RLDatix within ninety (90) days after expiration or termination. In the event of destruction of Client Data, RLDatix shall certify such destruction, in writing, to County. Notwithstanding the foregoing, RLDatix shall be permitted to retain any Client Data that is required to be retained as part of ongoing or contemplated litigation.

11.4 Transition Services: RLDatix may provide transition services to Client, upon expiration or termination of this Agreement, under an applicable Statement of Work signed by both Parties and at RLDatix' then current fee rate for such Professional Services.

Attachment I

HIPAA Business Associate Agreement
Addendum to Contract

Between the County of Riverside and Datix (USA) Inc.

This HIPAA Business Associate Agreement (the "Addendum") supplements, and is made part of the Underlying Agreement between the County of Riverside ("County") and Contractor and shall be effective as of the date the Underlying Agreement approved by both Parties (the "Effective Date").

RECITALS

WHEREAS, County and Contractor entered into the Underlying Agreement pursuant to which the Contractor provides services to County, and in conjunction with the provision of such services certain protected health information ("PHI") and/or certain electronic protected health information ("ePHI") may be created by or made available to Contractor for the purposes of carrying out its obligations under the Underlying Agreement; and,

WHEREAS, the provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Public Law 104-191 enacted August 21, 1996, and the Health Information Technology for Economic and Clinical Health Act ("HITECH") of the American Recovery and Reinvestment Act of 2009, Public Law 111-5 enacted February 17, 2009, and the laws and regulations promulgated subsequent thereto, as may be amended from time to time, are applicable to the protection of any use or disclosure of PHI and/or ePHI pursuant to the Underlying Agreement; and,

WHEREAS, County is a covered entity, as defined in the Privacy Rule; and,

WHEREAS, to the extent County discloses PHI and/or ePHI to Contractor or Contractor creates, receives, maintains, transmits, or has access to PHI and/or ePHI of County, Contractor is a business associate, as defined in the Privacy Rule; and,

WHEREAS, pursuant to 42 USC §17931 and §17934, certain provisions of the Security Rule and Privacy Rule apply to a business associate of a covered entity in the same manner that they apply to the covered entity, the additional security and privacy requirements of HITECH are applicable to business associates and must be incorporated into the business associate agreement, and a business associate is liable for civil and criminal penalties for failure to comply with these security and/or privacy provisions; and,

WHEREAS, the parties mutually agree that any use or disclosure of PHI and/or ePHI must be in compliance with the Privacy Rule, Security Rule, HIPAA, HITECH and any other applicable law; and,

WHEREAS, the parties intend to enter into this Addendum to address the requirements and obligations set forth in the Privacy Rule, Security Rule, HITECH and HIPAA as they apply to Contractor as a business associate of County, including the establishment of permitted and required uses and disclosures of PHI and/or ePHI created or received by Contractor during the course of performing functions, services and activities on behalf of County, and appropriate limitations and conditions on such uses and disclosures;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, the parties agree as follows:

1. **Definitions.** Terms used, but not otherwise defined, in this Addendum shall have the same meaning as those terms in HITECH, HIPAA, Security Rule and/or Privacy Rule, as may be amended from time to time.

   A. "Breach" when used in connection with PHI means the acquisition, access, use or disclosure of PHI in a manner not permitted under subpart E of the Privacy Rule which compromises the security or privacy of the PHI, and shall have the meaning given such term in 45 CFR §164.402.

      (1) Except as provided below in Paragraph (2) of this definition, acquisition, access, use, or disclosure of PHI in a manner not permitted by subpart E of the Privacy Rule is presumed to be a breach unless Contractor

demonstrates that there is a low probability that the PHI has been compromised based on a risk assessment of at least the following four factors:

(a) The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;

(b) The unauthorized person who used the PHI or to whom the disclosure was made;

(c) Whether the PHI was actually acquired or viewed; and

(d) The extent to which the risk to the PHI has been mitigated.

(2) Breach excludes:

(a) Any unintentional acquisition, access or use of PHI by a workforce member or person acting under the authority of a covered entity or business associate, if such acquisition, access or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under subpart E of the Privacy Rule.

(b) Any inadvertent disclosure by a person who is authorized to access PHI at a covered entity or business associate to another person authorized to access PHI at the same covered entity, business associate, or organized health care arrangement in which County participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted by subpart E of the Privacy Rule.

(c) A disclosure of PHI where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

B. "Business associate" has the meaning given such term in 45 CFR §164.501, including but not limited to a subcontractor that creates, receives, maintains, transmits or accesses PHI on behalf of the business associate.

C. "Data aggregation" has the meaning given such term in 45 CFR §164.501.

D. "Designated record set" as defined in 45 CFR §164.501 means a group of records maintained by or for a covered entity that may include: the medical records and billing records about individuals maintained by or for a covered health care provider; the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or, used, in whole or in part, by or for the covered entity to make decisions about individuals.

E. "Electronic protected health information" ("ePHI") as defined in 45 CFR §160.103 means protected health information transmitted by or maintained in electronic media.

F. "Electronic health record" means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff, and shall have the meaning given such term in 42 USC §17921(5).

G. "Health care operations" has the meaning given such term in 45 CFR §164.501.

H. "Individual" as defined in 45 CFR §160.103 means the person who is the subject of protected health information.

I. "Person" as defined in 45 CFR §160.103 means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

J. "Privacy Rule" means the HIPAA regulations codified at 45 CFR Parts 160 and 164, Subparts A and E.

K. "Protected health information" ("PHI") has the meaning given such term in 45 CFR §160.103, which includes ePHI.

L. "Required by law" has the meaning given such term in 45 CFR §164.103.

M. "Secretary" means the Secretary of the U.S. Department of Health and Human Services ("HHS").

N. "Security incident" as defined in 45 CFR §164.304 means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

O. "Security Rule" means the HIPAA Regulations codified at 45 CFR Parts 160 and 164, Subparts A and C.

P. "Subcontractor" as defined in 45 CFR §160.103 means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

Q. "Unsecured protected health information" and "unsecured PHI" as defined in 45 CFR §164.402 means PHI not rendered unusable, unreadable, or indecipherable to unauthorized persons through use of a technology or methodology specified by the Secretary in the guidance issued under 42 USC §17932(h)(2).

2. Scope of Use and Disclosure by Contractor of County's PHI and/or ePHI.

A. Except as otherwise provided in this Addendum, Contractor may use, disclose, or access PHI and/or ePHI as necessary to perform any and all obligations of Contractor under the Underlying Agreement or to perform functions, activities or services for, or on behalf of, County as specified in this Addendum, if such use or disclosure does not violate HIPAA, HITECH, the Privacy Rule and/or Security Rule.

B. Unless otherwise limited herein, in addition to any other uses and/or disclosures permitted or authorized by this Addendum or required by law, in accordance with 45 CFR §164.504(e)(2), Contractor may:

1) Use PHI and/or ePHI if necessary for Contractor's proper management and administration and to carry out its legal responsibilities; and,

2) Disclose PHI and/or ePHI for the purpose of Contractor's proper management and administration or to carry out its legal responsibilities, only if:

a) The disclosure is required by law; or,

b) Contractor obtains reasonable assurances, in writing, from the person to whom Contractor will disclose such PHI and/or ePHI that the person will:

i. Hold such PHI and/or ePHI in confidence and use or further disclose it only for the purpose for which Contractor disclosed it to the person, or as required by law; and,

ii. Notify County of any instances of which it becomes aware in which the confidentiality of the information has been breached; and,

3) Use PHI to provide data aggregation services relating to the health care operations of County pursuant to the Underlying Agreement or as requested by County; and,

4) De-identify all PHI and/or ePHI of County received by Contractor under this Addendum provided that the de-identification conforms to the requirements of the Privacy Rule and/or Security Rule and does not preclude timely payment and/or claims processing and receipt.

C. Notwithstanding the foregoing, in any instance where applicable state and/or federal laws and/or regulations are more stringent in their requirements than the provisions of HIPAA, including, but not limited to, prohibiting disclosure of mental health and/or substance abuse records, the applicable state and/or federal laws and/or regulations shall control the disclosure of records.

3. **Prohibited Uses and Disclosures.**

A. Contractor may neither use, disclose, nor access PHI and/or ePHI in a manner not authorized by the Underlying Agreement or this Addendum without patient authorization or de-identification of the PHI and/or ePHI and as authorized in writing from County.

B. Contractor may neither use, disclose, nor access PHI and/or ePHI it receives from County or from another business associate of County, except as permitted or required by this Addendum, or as required by law.

C. Contractor agrees not to make any disclosure of PHI and/or ePHI that County would be prohibited from making.

D. Contractor shall not use or disclose PHI for any purpose prohibited by the Privacy Rule, Security Rule, HIPAA and/or HITECH, including, but not limited to 42 USC §17935 and §17936. Contractor agrees:

1) Not to use or disclose PHI for fundraising , unless pursuant to the Underlying Agreement and only if permitted by and in compliance with the requirements of 45 CFR §164.514(f) or 45 CFR §164.508;

2) Not to use or disclose PHI for marketing, as defined in 45 CFR §164.501, unless pursuant to the Underlying Agreement and only if permitted by and in compliance with the requirements of 45 CFR §164.508(a)(3);

3) Not to disclose PHI, except as otherwise required by law, to a health plan for purposes of carrying out payment or health care operations, if the individual has requested this restriction pursuant to 42 USC §17935(a) and 45 CFR §164.522, and has paid out of pocket in full for the health care item or service to which the PHI solely relates; and,

4) Not to receive, directly or indirectly, remuneration in exchange for PHI, or engage in any act that would constitute a sale of PHI, as defined in 45 CFR §164.502(a)(5)(ii), unless permitted by the Underlying Agreement and in compliance with the requirements of a valid authorization under 45 CFR §164.508(a)(4). This prohibition shall not apply to payment by County to Contractor for services provided pursuant to the Underlying Agreement.

4. **Obligations of County.**

A. County agrees to make its best efforts to notify Contractor promptly in writing of any restrictions on the use or disclosure of PHI and/or ePHI agreed to by County that may affect Contractor's ability to perform its obligations under the Underlying Agreement, or this Addendum.

B. County agrees to make its best efforts to promptly notify Contractor in writing of any changes in, or revocation of, permission by any individual to use or disclose PHI and/or ePHI, if such changes or revocation may affect Contractor's ability to perform its obligations under the Underlying Agreement, or this Addendum.

C. County agrees to make its best efforts to promptly notify Contractor in writing of any known limitation(s) in its notice of privacy practices to the extent that such limitation may affect Contractor's use or disclosure of PHI and/or ePHI.

D. County agrees not to request Contractor to use or disclose PHI and/or ePHI in any manner that would not be permissible under HITECH, HIPAA, the Privacy Rule, and/or Security Rule.

E. County agrees to obtain any authorizations necessary for the use or disclosure of PHI and/or ePHI, so that Contractor can perform its obligations under this Addendum and/or Underlying Agreement.

5. **Obligations of Contractor.** In connection with the use or disclosure of PHI and/or ePHI, Contractor agrees to:

A. Use or disclose PHI only if such use or disclosure complies with each applicable requirement of 45 CFR §164.504(e). Contractor shall also comply with the additional privacy requirements that are applicable to covered entities in HITECH, as may be amended from time to time.

B. Not use or further disclose PHI and/or ePHI other than as permitted or required by this Addendum or as required by law. Contractor shall promptly notify County if Contractor is required by law to disclose PHI and/or ePHI.

C. Use appropriate safeguards and comply, where applicable, with the Security Rule with respect to ePHI, to prevent use or disclosure of PHI and/or ePHI other than as provided for by this Addendum.

D. Mitigate, to the extent practicable, any harmful effect that is known to Contractor of a use or disclosure of PHI and/or ePHI by Contractor in violation of this Addendum.

E. Report to County any use or disclosure of PHI and/or ePHI not provided for by this Addendum or otherwise in violation of HITECH, HIPAA, the Privacy Rule, and/or Security Rule of which Contractor becomes aware, including breaches of unsecured PHI as required by 45 CFR §164.410.

F. In accordance with 45 CFR §164.502(e)(1)(ii), require that any subcontractors that create, receive, maintain, transmit or access PHI on behalf of the Contractor agree through contract to substantially similar restrictions and conditions to those that apply to Contractor with respect to such PHI and/or ePHI, including the restrictions and conditions pursuant to this Addendum.

G. Make available to County or the Secretary, in the time and manner designated by County or Secretary, Contractor's internal practices, books and records relating to the use, disclosure and privacy protection of PHI received from County, or created or received by Contractor on behalf of County, for purposes of determining, investigating or auditing Contractor's and/or County's compliance with the Privacy Rule.

H. Request, use or disclose only the minimum amount of PHI necessary to accomplish the intended purpose of the request, use or disclosure in accordance with 42 USC §17935(b) and 45 CFR §164.502(b)(1).

I. Comply with requirements of satisfactory assurances under 45 CFR §164.512 relating to notice or qualified protective order in response to a third party's subpoena, discovery request, or other lawful process for the disclosure of PHI, which Contractor shall promptly notify County upon Contractor's receipt of such request from a third party.

J. Not require an individual to provide patient authorization for use or disclosure of PHI as a condition for treatment, payment, enrollment in any health plan (including the health plan administered by County), or eligibility of benefits, unless otherwise excepted under 45 CFR §164.508(b)(4) and authorized in writing by County.

K. Use appropriate administrative, technical and physical safeguards to prevent inappropriate use, disclosure, or access of PHI and/or ePHI.

L. Obtain and maintain knowledge of applicable laws and regulations related to HIPAA and HITECH, as may be amended from time to time.

M. Comply with the requirements of the Privacy Rule that apply to the County to the extent Contractor is to carry out County's obligations under the Privacy Rule.

N. Take reasonable steps to cure or end any pattern of activity or practice of its subcontractor of which Contractor becomes aware that constitute a material breach or violation of the subcontractor's obligations under the business associate contract with Contractor, and if such steps are unsuccessful, Contractor agrees to terminate its contract with the subcontractor if feasible.

6. **Access to PHI, Amendment and Disclosure Accounting.** Contractor agrees to:

A. **Access to PHI, including ePHI.** To the extent that Contractor maintains PHI in a designated record set, provide access to PHI, including ePHI if maintained electronically, in a designated record set to County or an individual as directed by County, within five (5) days of request from County, to satisfy the requirements of 45 CFR §164.524.

B. **Amendment of PHI.** To the extent that Contractor maintains PHI in a designated record set, make PHI available for amendment and incorporate amendments to PHI in a designated record set County directs or agrees to at the request of an individual, within fifteen (15) days of receiving a written request from County, in accordance with 45 CFR §164.526.

C. **Accounting of disclosures of PHI and electronic health record.** Assist County to fulfill its obligations to provide accounting of disclosures of PHI under 45 CFR §164.528 and, where applicable, electronic health records under 42 USC §17935(c) if Contractor uses or maintains electronic health records. Contractor shall:

1) Document such disclosures of PHI and/or electronic health records, and information related to such disclosures, as would be required for County to respond to a request by an individual for an accounting of disclosures of PHI and/or electronic health record in accordance with 45 CFR §164.528.

2) Within fifteen (15) days of receiving a written request from County, provide to County or any individual as directed by County information collected in accordance with this section to permit County to respond to a request by an individual for an accounting of disclosures of PHI and/or electronic health record.

3) Make available for County information required by this Section 6.C for six (6) years preceding the individual's request for accounting of disclosures of PHI, and for three (3) years preceding the individual's request for accounting of disclosures of electronic health record.

7. **Security of ePHI.** In the event County discloses ePHI to Contractor or Contractor needs to create, receive, maintain, transmit or have access to County ePHI, in accordance with 42 USC §17931 and 45 CFR §164.314(a)(2)(i), and §164.306, Contractor shall:

A. Comply with the applicable requirements of the Security Rule, and implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI that Contractor creates, receives, maintains, or transmits on behalf of County in accordance with 45 CFR §164.308, §164.310, and §164.312;

B. Comply with each of the requirements of 45 CFR §164.316 relating to the implementation of policies, procedures and documentation requirements with respect to ePHI;

C. Protect against any reasonably anticipated threats or hazards to the security or integrity of ePHI;

D. Protect against any reasonably anticipated uses or disclosures of ePHI that are not permitted or required under the Privacy Rule;

E. Ensure compliance with the Security Rule by Contractor's workforce;

F. In accordance with 45 CFR §164.308(b)(2), require that any subcontractors that create, receive, maintain, transmit, or access ePHI on behalf of Contractor agree through contract to the same restrictions and requirements contained in this Addendum and comply with the applicable requirements of the Security Rule;

G. Report to County any security incident of which Contractor becomes aware, including breaches of unsecured PHI as required by 45 CFR §164.410; and,

H. Comply with any additional security requirements that are applicable to covered entities in Title 42 (Public Health and Welfare) of the United States Code, as may be amended from time to time, including but not limited to HITECH.

8. **Breach of Unsecured PHI.** In the case of breach of unsecured PHI, Contractor shall comply with the applicable provisions of 42 USC §17932 and 45 CFR Part 164, Subpart D, including but not limited to 45 CFR §164.410.

A. **Discovery and notification.** Following the discovery of a breach of unsecured PHI, Contractor shall notify County in writing of such breach without unreasonable delay and in no case later than 60 calendar days after discovery of a breach, except as provided in 45 CFR §164.412.

1) **Breaches treated as discovered.** A breach is treated as discovered by Contractor as of the first day on which such breach is known to Contractor or, by exercising reasonable diligence, would have been known to Contractor, which includes any person, other than the person committing the breach, who is an employee, officer, or other agent of Contractor (determined in accordance with the federal common law of agency).

2) **Content of notification.** The written notification to County relating to breach of unsecured PHI shall include, to the extent possible, the following information if known (or can be reasonably obtained) by Contractor:

a) The identification of each individual associated with County whose unsecured PHI has been, or is reasonably believed by Contractor to have been accessed, acquired, used or disclosed during the breach;

b) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;

c) A description of the types of unsecured PHI involved in the breach, such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved;

d) Any steps individuals should take to protect themselves from potential harm resulting from the breach;

e) A brief description of what Contractor is doing to investigate the breach, to mitigate harm to individuals, and to protect against any further breaches; and,

f) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, web site, or postal address.

B. **Cooperation.** With respect to any breach of unsecured PHI reported by Contractor, Contractor shall cooperate with County and shall provide County with any information requested by County to enable County to fulfill in a timely manner its own reporting and notification obligations, including but not limited to providing notice to individuals, prominent media outlets and the Secretary in accordance with 42 USC §17932 and 45 CFR §164.404, §164.406 and §164.408.

C. **Delay of notification authorized by law enforcement.** If Contractor delays notification of breach of unsecured PHI pursuant to a law enforcement official's statement that required notification, notice or posting would impede a criminal investigation or cause damage to national security, Contractor shall maintain documentation sufficient to demonstrate its compliance with the requirements of 45 CFR §164.412.

D. **Payment of costs.** With respect to any breach of unsecured PHI caused solely by the Contractor's failure to comply with one or more of its obligations under this Addendum and/or the provisions of HITECH, HIPAA, the Privacy Rule or the Security Rule, Contractor agrees to pay any and all costs associated with providing all legally required notifications to individuals, media outlets, and the Secretary. This provision shall not be

construed to limit or diminish Contractor's obligations to indemnify, defend and hold harmless County under Section 9 of this Addendum.

E. **Documentation.** Pursuant to 45 CFR §164.414(b), in the event Contractor's use or disclosure of PHI and/or ePHI violates the Privacy Rule, Contractor shall maintain documentation sufficient to demonstrate that all notifications were made by Contractor as required by 45 CFR Part 164, Subpart D, or that such use or disclosure did not constitute a breach, including Contractor's completed risk assessment and investigation documentation.

F. **Additional State Reporting Requirements.** The parties agree that this Section 8.G applies only if and/or when County, in its capacity as a licensed clinic, health facility, home health agency, or hospice, is required to report unlawful or unauthorized access, use, or disclosure of medical information under the more stringent requirements of California Health & Safety Code §1280.15. For purposes of this Section 8.G, "unauthorized" has the meaning given such term in California Health & Safety Code §1280.15(j)(2).

1) Contractor agrees to assist County to fulfill its reporting obligations to affected patients and to the California Department of Public Health ("CDPH") in a timely manner under the California Health & Safety Code §1280.15.

2) Contractor agrees to report to County any unlawful or unauthorized access, use, or disclosure of patient's medical information without unreasonable delay and no later than two (2) business days after Contractor detects such incident. Contractor further agrees such report shall be made in writing, and shall include substantially the same types of information listed above in Section 8.A.2 (Content of Notification) as applicable to the unlawful or unauthorized access, use, or disclosure as defined above in this section, understanding and acknowledging that the term "breach" as used in Section 8.A.2 does not apply to California Health & Safety Code §1280.15.

9. **Hold Harmless/Indemnification and Limitation of Liability.**

A. Contractor agrees to indemnify and hold harmless County, all Agencies, Districts, Special Districts and Departments of County, their respective directors, officers, Board of Supervisors, elected and appointed officials, employees, agents and representatives from any liability whatsoever, based or asserted upon any services of Contractor, its officers, employees, subcontractors, agents or representatives Directly arising out of Contractor's, its officers', agents', employees', subcontractors' or representatives' breach of this Addendum.

B. With respect to any action or claim subject to indemnification herein by Contractor, Contractor shall, at their sole cost, have the right to use counsel of their choice, and shall have the right to adjust, settle, or compromise any such action or claim without the prior consent of County; provided, however, that any such adjustment, settlement or compromise in no manner whatsoever limits or circumscribes Contractor's indemnification to County as set forth herein. Contractor's obligation to defend, indemnify and hold harmless County shall be subject to County having given Contractor written notice within a reasonable period of time of the claim or of the commencement of the related action, as the case may be, and information and reasonable assistance, at Contractor's expense, for the defense or settlement thereof. Contractor's obligation hereunder shall be satisfied when Contractor has provided to County the appropriate form of dismissal relieving County from any liability for the action or claim involved.

C. The specified insurance limits required in the Underlying Agreement of this Addendum shall in no way limit or circumscribe Contractor's obligations to indemnify and hold harmless County herein from third party claims arising from issues of this Addendum.

D. In the event there is conflict between this clause and California Civil Code §2782, this clause shall be interpreted to comply with Civil Code §2782. Such interpretation shall not relieve the Contractor from indemnifying County to the fullest extent allowed by law.

E. In the event there is a conflict between this indemnification clause and an indemnification clause contained in the Underlying Agreement of this Addendum, this indemnification shall only apply to the subject issues included within this Addendum.

F. Neither party will be liable to the other party for indirect, incidental, consequential, special or exemplary damages arising from this Addendum in any manner, or from the contractual relationship established herein. Each party's total liability for any action, claim, or costs (including costs incurred in connection with business associate's mitigation obligations herein) will not exceed the total amount paid to Contractor by County under the applicable Underlying Agreement for the twelve (12) month subscription period within which an action or claim has arisen. The limitations above apply whether an action is in contract or tort and regardless of the theory of liability. Notwithstanding any provision of the Underlying Agreement to the contrary, the limitation of each party's liability arising out of or in connection with this Addendum will be governed solely by this Section 9(f).

10. **Term.** This Addendum shall commence upon the Effective Date and shall terminate when all PHI and/or ePHI provided by County to Contractor, or created or received by Contractor on behalf of County, is destroyed or returned to County, or, if it is infeasible to return or destroy PHI and/ePHI, protections are extended to such information, in accordance with section 11.B of this Addendum.

11. **Termination.**

A. **Termination for Breach of Contract.** A breach of any provision of this Addendum by either party shall constitute a material breach of the Underlying Agreement and will provide grounds for terminating this Addendum and the Underlying Agreement with or without an opportunity to cure the breach, notwithstanding any provision in the Underlying Agreement to the contrary. Either party, upon written notice to the other party describing the breach, may take any of the following actions:

1) Terminate the Underlying Agreement and this Addendum, effective immediately, if the other party breaches a material provision of this Addendum.

2) Provide the other party with an opportunity to cure the alleged material breach and in the event the other party fails to cure the breach to the satisfaction of the non-breaching party in a timely manner, the non-breaching party has the right to immediately terminate the Underlying Agreement and this Addendum.

3) If termination of the Underlying Agreement is not feasible, the breaching party, upon the request of the non-breaching party, shall implement, at its own expense, a plan to cure the breach and report regularly on its compliance with such plan to the non-breaching party.

B. **Effect of Termination.**

1) After termination of this Addendum, for any reason, and upon written notice from County, Contractor shall return or, if instructed in writing by County, destroy all PHI and/or ePHI received from County, or created or received by the Contractor on behalf of County, and, in the event of destruction, Contractor shall certify such destruction, in writing, to County. If no written notice is received from County within thirty (30) days of termination then Contractor may destroy all PHI or ePHI unless otherwise prohibited by law. This provision shall apply to all PHI and/or ePHI which are in the possession of subcontractors or agents of Contractor. Contractor shall retain no copies of PHI and/or ePHI, except as provided below in paragraph (2) of this section.

2) In the event that Contractor determines that returning or destroying the PHI and/or ePHI is not feasible, Contractor shall provide written notification to County of the conditions that make such return or destruction not feasible. Upon determination by Contractor that return or destruction of PHI and/or ePHI is not feasible, Contractor shall extend the protections of this Addendum to such PHI and/or ePHI and limit further uses and disclosures of such PHI and/or ePHI to those purposes which make the return or destruction not feasible, for so long as Contractor maintains such PHI and/or ePHI.

12. **General Provisions.**

A. **Retention Period.** Whenever Contractor is required to document or maintain documentation pursuant to the terms of this Addendum, Contractor shall retain such documentation for 6 years from the date of its creation or as otherwise prescribed by law, whichever is later.

B. **Amendment.** The parties agree to take such action as is necessary to amend this Addendum from time to time as is necessary for County to comply with HITECH, the Privacy Rule, Security Rule, and HIPAA generally.

C. **Survival.** The obligations of Contractor under Sections 3, 5, 6, 7, 8, 9, 11.B and 12.A of this Addendum shall survive the termination or expiration of this Addendum.

D. **Regulatory and Statutory References.** A reference in this Addendum to a section in HITECH, HIPAA, the Privacy Rule and/or Security Rule means the section(s) as in effect or as amended.

E. **Conflicts.** The provisions of this Addendum shall prevail over any provisions in the Underlying Agreement that conflict or appear inconsistent with any provision in this Addendum.

F. **Interpretation of Addendum.**

1) This Addendum shall be construed to be part of the Underlying Agreement as one document. The purpose is to supplement the Underlying Agreement to include the requirements of the Privacy Rule, Security Rule, HIPAA and HITECH.
2) Any ambiguity between this Addendum and the Underlying Agreement shall be resolved to permit County to comply with the Privacy Rule, Security Rule, HIPAA and HITECH generally.

G. **Notices to County.** All notifications required to be given by Contractor to County pursuant to the terms of this Addendum shall be made in writing and delivered to the County both by fax and to both of the addresses listed below by either registered or certified mail return receipt requested or guaranteed overnight mail with tracing capability, or at such other address as County may hereafter designate. All notices to County provided by Contractor pursuant to this Section shall be deemed given or made when received by County.

County HIPAA Privacy Officer: HIPAA Privacy Manager

County HIPAA Privacy Officer Address:	26520 Cactus Avenue, Moreno Valley, CA 92555
County HIPAA Privacy Office Email:	R.Compliance@ruhealth.org

County HIPAA Privacy Officer Phone Number: (951) 486-4659

EXHIBIT D – Standard Support Plan

This Exhibit D is to document the Standard Support Plan as it existed as the time of signing the Agreement. However, the official version of the Standard Support Plan remains the version found at https://www.rldatix.com/en-nam/msa.

STANDARD SUPPORT PLAN

Version 1.0

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Version Control

Version	Date	Notes
1.0	May 1, 2021	

1 Welcome to the RLDatix Standard Support Plan

RLDatix has created this document with the following objectives in mind:

- To outline the scope of support services included in the Standard Support Plan once a customer's software is live and fully operational (post-implementation), provided the customer's account is in good standing.
- To help the customer's named users effectively access RLDatix support services.
- To reflect the Service Levels that form part of the contract between the customer and RLDatix.

RLDatix is not obligated to provide support for issues caused by use of the software that is not in accordance with the specifications and/or the terms of this Plan.

2 Definition of Support

Support is defined as technical support or break/fix services that typically include remote troubleshooting and basic usability assistance.

3 Definition of Installation Types

This Plan covers the following types of installation of RLDatix software:

On-premise: Refers to a customer that has installed the RLDatix software within their own data center, on their own servers. Customer's IT is responsible for all maintenance of the hardware, environments and other systems necessary to run the RLDatix software.

Hosted: Refers to a customer with a unique instance of their software hosted in the RLDatix data center. RLDatix is responsible for the maintenance of the software and environment. Customer IT still required to maintain systems in the customer environment that interface with the RLDatix software.

Capped: Refers to an RL6 customer with a hosted installation of only select modules and a limited number of annual hours available for support services, as specified on the Order Form.

SaaS: SaaS, or Software as a Service, refers to a customer hosted in a cloud environment (e.g. AWS), where RLDatix is responsible for the maintenance of the software and environment. Customer IT is required to maintain systems in the customer environment that interface with the RLDatix software and environment.

4 Named Users Permitted to Contact RLDatix Support

Named users are those people that are permitted to contact RLDatix Support by phone or ticketing for assistance.

- For customers using RLDatix products where system administration is designated by a license type, the number of named users will equal the number of system administration licenses purchased.

- For customers using RLDatix products where system administration is based on permissions and not associated with a license type, the customer may designate up to two (2) named users per site.

Customers may also designate up to five (5) named IT users in addition to the above.

Additional named users must be included on the Order Form.

Front-line staff should use the customer's own internal Help Desk support mechanism.

Named users are required to set up access to RLDatix SupportHUB and to also maintain their user profiles. Named users will receive confirmation of their SupportHUB login credentials within three (3) business days.

5 Supported Versions & Environments

RLDatix will provide support for the current SaaS version on each release channel, as may be amended from time to time.

For on-premise and hosted installations, RLDatix will provide support for the current version and version(s) within one (1) year of release of the current version, as may be amended from time to time.

RLDatix supports up to two (2) environments, e.g. test/staging and production, as applicable for the particular product suite.

6 Services Included in the Standard Support Plan

The following services are included in the Standard Support Plan:

a) Remote and online support to named users related to issues considered as incidents (errors), questions, and service requests.
b) Access by named users to online support resources available via SupportHUB including:
    i) Tickets for reporting and tracking support inquiries
    ii) Knowledgebase for common and known support and troubleshooting guidance iii) Education for access to current materials, guides, lessons and recorded videos.
c) Access to the RLDatix HUB Community to connect with other customers for the purposes of collaboration and sharing of knowledge and ideas.

d) Access to content such as case studies, webinars, resource libraries, and whitepapers on industry topics.
e) Access to new software versions and related orientation materials and/or new release orientation webinars.
f) Support of interfaces, lookups and integrations purchased from RLDatix.
g) Exclusive opportunities to participate in RLDatix sponsored events such as user groups, webinars and tradeshow receptions (registration fees may apply).
h) Submission and voting on product ideas and suggestions.
i) Other requests for service that are deemed to be within the scope of the Standard Support Plan by RLDatix, as outlined in a regional services catalogue, where applicable.

RLDatix reserves the right to monitor a customer's support usage by tracking the amount of time RLDatix resources spend responding to tickets, questions and inquiries and assisting the customer. Where that usage is excessive and/or atypical, RLDatix reserves the right to propose alternative service options to address the customer's needs, including potential adjustments to fees.

7 Additional Services Available for Purchase

The following services are offered outside of the Standard Support Plan and may be purchased by the customer:

a) Premium services and resources associated with higher level Support Plans or other addon services.
b) Custom training services in lieu of using self-paced online resources and/or other standard training offered by RLDatix from time to time.
c) Software configuration, forms design and report design assistance deemed to be outside of the scope of support.
d) Legacy data conversion/migration into the RLDatix system.
e) Set up, configuration and maintenance of 3rd party and data warehouse imports/exports, unless specified on the Order Form.
f) Support for legacy software environments and data extraction for archive purposes.
g) Support for more than two (2) environments.
h) Additional named users.
i) Technical services for on-premise customers related to installation of new software versions, server migrations, technical consultation and stand-by services when customer is performing their own technical work.
j) Other service requests where request is deemed by RLDatix to be a chargeable service.
k) Onsite support services where deemed necessary by RLDatix and customer. Support that requires RLDatix to attend at customer's premises shall be at the customer's expense.

8 Exclusions

The following items are excluded:

a) Correction of errors caused by:

i) operation of the software in a manner other than that currently specified by RLDatix.
ii) modification, revision, variation, translation or alteration of the software not permitted by RLDatix.
iii) operation of the software in an environment that does not meet the technical specifications for the applicable software version.
iv) operation of the software on an unsupported version at the time of the defect. v) use of the software by a person not permitted by RLDatix vi) support for use of computer programs other than the RLDatix software. vii) failure of the customer to provide suitably qualified and adequately trained operating and programming staff for the operation of the software.
viii) modifications to the database structure and/or direct activities within the database (all environments).
ix) hardware fault or operating system malfunction. x) customer's failure to comply with this Plan.
xi) errors or defects that are the subject of a warranty under another agreement.
xii) mobile devices or hardware.

b) Maintenance of customer equipment or hardware.
c) Diagnosis or rectification of faults not associated with the software.
d) Furnishing or maintenance of accessories, attachments, supplies, consumables or associated items, whether or not manufactured or distributed by RLDatix.
e) Unique customer-specific vendor access requirements such as training of RLDatix resources, reapplying for access, frequent requirements for resetting of accounts, etc. Customers will need to declare their unique requirements and RLDatix will assess if acceptable within the scope of support services.
f) Completion of customer-specific documents such as vendor security questionnaires required after purchase. RLDatix provides a standard security assessment reference document that a customer can use to support and complete their unique questionnaire.
g) Development of custom database queries and triggers.

If an error is confirmed to be due to any of the above factors, or other act of commission or omission of the customer, RLDatix reserves the right to deny support and/or bill the customer at the then current hourly rate for all effort in identifying, investigating and troubleshooting the error.

9 Customer Responsibilities

As a partner in supporting the RLDatix software, the customer is responsible for the following:

a) Compliance to the Standard Support Plan.
b) Staying current with the supported software version as outlined in Section 5 and the applicable RLDatix specifications. For customers with an On-Premise installation, this includes performing their own software updates where RLDatix has assessed this to be possible based on the specifications and capabilities of the update tool and compatibility to the customer's technical environment.

c) Designating key personnel who will act as the named users to access RLDatix Support and maintaining profiles via RLDatix SupportHUB to ensure that RLDatix has current information on named users.
d) Setting up an internal "Help Desk" support mechanism with trained, skilled and available resource(s) to support end users with everyday questions, conduct initial investigation and complete thorough troubleshooting before referring issue to RLDatix Support. Help Desk responsibilities include:
    i) User set up and management; user login issues, resetting passwords
    ii) User desktop support, including email and printing issues; PC related issues & logs; install/re-install of OS and software links
    iii) Browser issues related to security settings, compatibility and other advanced settings, user rights, security zones, group policies, phishing filters, Active X control permissions, profiles, etc.
    iv) Anti-virus issues
    v) Troubleshooting related to interface performance
    vi) Performing internal QA testing as per internal policies and procedures vii) Troubleshooting related to end-user mobile devices/hardware viii) User membership to active directory groups ix) LDAP server/domain login issues
    x) Maintaining approved network bandwidth/throughput and connectivity
e) Actively participating in the RLDatix support process by:
    i) Reporting the necessary facts and information via the RLDatix support ticketing system including steps taken to reproduce the issue and supporting materials. NOTE: It the customer's responsibility to ensure that no PHI is provided to RLDatix via tickets or email. Should PHI need to be provided for the purposes of rendering support, a secure transfer protocol will be established for the transmission of the data.
    ii) Taking timely action on advice/recommendations provided by RLDatix, and timely response to communications from RLDatix .
    iii) Coordinating internal resources and arranging timely access to the necessary internal business contacts and/or qualified IT contacts with appropriate system rights for further information gathering and joint troubleshooting, when necessary.
f) Having an established process to provide internal software orientation and training to new hires/replacements, including key roles such as the System Administrator.
g) Informing RLDatix Support when the customer's local environment and security has been materially compromised so that RLDatix does not risk exposure to viruses and other security issues.
h) For customers with an On-Premise installation, providing remote access through a secure vendor priviledged access management platform (e.g. SecureLink or comparable alternative) to all environments and necessary systems for the purposes of rendering assistance.
i) Assuming any associated costs related to unique software/hardware or licensing that is required in the customer's environment. This includes vendor access costs if customer unable to use RLDatix recommended method.
j) Establishment and compliance to internal change management process to ensure necessary notifications, approvals and tracking occurs to avoid delays in RLDatix performing its duties due to change management oversights.
k) Arranging, attending and facilitating any meetings/calls between RLDatix and other 3rd parties such as other vendors, reporting bodies, etc.

10 Contacting RLDatix Support

An issue is considered received by RLDatix when it is either:

- Reported by phone to the RLDatix designated support line (verbally or by voice mail) for Severity Level 1 issues only.
- Reported by ticket for Severity level 2-4 issues.

10.1 Types of Issues

Customers may contact RLDatix for assistance with any of the following types of issues:

- **Incident:** An error related to software technical functionality which may/may not be due to a defect.
- **Question:** An inquiry on how to use specific features of the software, or how to perform a specific function.
- **Service Request:** A request for assistance related to configuration or services rendered by RLDatix. Depending on the nature of the request, assistance may or may not be within the scope of support services.
- **Update Related Issue:** A question or problem related to the planning, installation or testing of a software update for customers with an On-Premise installation of the RLDatix software.

10.2 Reproducing Issues

At the time of contact, the Customer shall describe the nature of the issue and provide sufficient details of the circumstances of its occurrence, at RLDatix's discretion, for RLDatix to be able to reproduce the issue and commence efforts.

RLDatix must be able to reproduce issues in order to resolve them. The Customer agrees to cooperate and work closely with RLDatix to reproduce issues, including conducting diagnostic or troubleshooting activities as reasonably requested and appropriate. The Customer agrees to provide RLDatix with remote access to the software and environments, where necessary, for the purposes of troubleshooting.

10.3 Hours of Support

RLDatix Support is available on Business Days, excluding holidays, from 8:30am to 5:30pm. Business Days are defined as Monday to Friday, except for the MEA region, where Business Days are defined as Sunday to Thursday.

10.4 Contacting by Telephone

For Severity Level 1 issues only, users are encouraged to phone RLDatix Support. Severity Level 1 issues may also be reported by ticket, if preferred.

Telephone numbers are as follows:

- North America:
  - RL6: 1-888-737-7444
  - DatixWeb/DCIQ: 1-800-596-5015
  - SRM: 1-855-753-2849
  - Verge: 843-628-4168
  - PolicyStat: 317-644-1296
  - PolicyMedical: 1-888-697-6331
- UKE: +44 0 20 8971 1946
- APAC:
  - RMI/DCIQ: +61 3 9686 5456
  - RL6 (Australia): +1 300 885 675
  - RL6 (New Zealand): +0800 885 675
- MEA: +966 55 398 9256

Customers may be prompted to leave a voice message on the designated support line if resources are unavailable. A voice message left on the designated support line for Severity Level 1 falls within the service level. Messages are retrieved regularly and will be triaged and processed by the next available support representative in the order in which they were received.

Customers should not leave voice mail messages to RLDatix staff at their personal phone extensions, nor send emails to personal email addresses.

10.5 Submitting a Ticket

For Severity Level 2-4 issues, users are required to only contact RLDatix Support by submitting a support ticket via the RLDatix SupportHUB, https://hub.rldatix.com/ . Each ticket will be assigned a unique tracking number and tickets are automatically routed to the applicable RLDatix Support team for response.

The benefits of submitting a ticket are:

- facilitates communication back and forth between the customer and RLDatix support staff while the issue is worked on
- central documentation of the issue, including attachments and subsequent communication within the ticket
- time stamps the ticket and all activities to track status and timeliness of resolution

- allows RLDatix to route the ticket to an available resource
- allows all those interested in the ticket to view the status of the ticket and post notes
- ensures that communication is not lost in personal email inboxes and voicemail.

11 Service Levels

RLDatix offers the following service levels and will use commercially reasonable efforts to resolve a reproducible issue in a timely manner.

Actual resolution time will depend on the nature of the ticket and the resolution steps.

A resolution may consist of any of the following:

- Solution to the issue so that the software is functional
- Fix within the permitted scope of support services
- Workaround that achieves end result
- Temporary fix compatible to the version, if deemed possible by RLDatix
- Update of software by customer or RLDatix, depending on type of installation
- Confirmation that the software is performing as designed with no further action by RLDatix
- Instruction to customer if the issue is caused by a condition within the customer's control
- Confirmation of issue and referral to RLDatix Product Team for future release.

Severity	Definition	Initial Response Time
Severity 1 Critical	Production system is inoperable affecting all users and/or data integrity is compromised.	Within 1 business hour of receipt of reported issue by phone or ticket
Severity 2 High	Production system is operable with a major component malfunctioning that affects all users.	Within 1 business day of receipt of reported issue by ticket
Severity 3 Medium	Production system is operable with a minor/isolated component malfunctioning that affects a subset of users.	Within 3 business days of receipt of reported issue by ticket
Severity 4 Low	Production system is operable with a minor/isolated component malfunctioning that affects a single user, or where request is cosmetic, an inquiry, question or request for service.	Within 5 business days of receipt of reported issue by ticket

12 Product Ideas & Suggestions

Product ideas and suggestions may be submitted via the RLDatix HUB and are not covered under the Service Levels.

All ideas and suggestions are considered by RLDatix's Product Management team, taking into consideration overall benefit to the software, value to broader customer-base, feasibility of the ideas and costs. RLDatix does not guarantee an individual customer's request for change will be incorporated into the standard product. Communication and response to product ideas and suggestions is via RLDatix HUB.

13 Virtual Environment for On-Premise Installation

For customers with an On-Premise installation, if issues are detected with the software functionality and confirmed by RLDatix to be related to the virtual environment, it is the customer's responsibility to identify and change the configuration of the virtual environment until the issue is resolved. This may require moving the virtual environment onto a different host, if the existing one is not able to accommodate the necessary changes. RLDatix assumes that the customer has in-house expertise for virtual server administration.

If, despite all reasonable efforts, the software still does not function properly, it is the customer's responsibility to contact the vendor of the virtual software in which the RLDatix product(s) is being hosted for support and help with issue resolution.

RLDatix reserves the right to request that the software be moved to a hardware stand-alone server(s) as a part of the efforts to troubleshoot the software problem. If the issue cannot be reproduced in the hardware stand-alone server(s) configuration and cannot be resolved in the virtual environment, the customer should be prepared to abandon the virtual environment and use the software in the standalone hardware server(s) configuration.

14 Escalation Procedure

If at any time a customer feels that their support expectations have not been met, the customer may escalate their concern to a manager. Escalation will receive prompt attention and management focus.

If the customer's expectations are still not met, then the concern can be further escalated to a member of the RLDatix Executive Leadership Team.

15 What if My Fees are in Arrears?

In the event that a customer contacts RLDatix for support and their account is not in good standing, the customer will be directed to the RLDatix Finance team.

RLDatix Finance reserves the right to suspend all services for accounts that are not in good standing. This includes suspension of support services for both technical and non-technical issues, delivery of software fixes/updates, and all other services related to training, consultation, implementation, and Support Plans.

16 Changes to Standard Support Plan

RLDatix reserves the right to change its Standard Support Plan from time to time in its sole discretion. The most current version of the Standard Support Plan will be posted electronically at https://www.rldatix.com/en-us/msa.

This Agreement is made and entered into by and between the COUNTY OF RIVERSIDE, hereinafter

Final Audit Report 2024-03-22

Created:	2024-03-21
By:	israel gomez (israel.gomez1987@gmail.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAcNK07DOxts7H86wp0ESFFyX-Vhbbl0aD

"This Agreement is made and entered into by and between the COUNTY OF RIVERSIDE, hereinafter" History

Document created by israel gomez (israel.gomez1987@gmail.com)
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Agreement completed.
2024-03-22 - 6:33:40 PM GMT

ROUTE SLIP

From: Israel Gomez
Date: *March 18, 2024*

Regarding: SSJ Request for Datixweb to RL6 Platform

Name	Title	Reviewed
Amparo Quintero	Admin SVCS Manager I	AQ
Joe Zamora	*CFO*	JZ
Jen Cruikshank	*CEO*	JLC

- Attached are the following and requires approval:
  - *Single Source Justification (SSJ) – required for non-competitive Agreements in excess of $5,000*

Amount – Total contract amount for this Agreement is $910,198.16

Period of Performance – FY23/24 to FY28/29

- Service – Request for Datix RL6 Patient Safety, Risk Management & Quality Improvement Software Solutions

Hospital benefits – The positive downstream effect of such robust program can help minimize claims and litigations from ineffective processes within a system. Three crucial advantages with this single source requisition: (a) we are currently using the old and obsolete version of the Datix system with outdated functionality, the transition will require re-mapping these functions without having to learn a new system and hiring new analyst/IT to manage or figure out the new operating systems; (b) RL Datix provide a comprehensive solution that is in alignment with the PCAST recommendations as well as leading the industry in patient safety Governance, Risk Management, Compliance and Accreditation; and (c) we currently do not have a robust risk management program that can link filed claims to preventable harms. By implementing the Datix (USA) Inc. system, it ensures compliance and enable collaborative efforts to compare and benchmark safety data. This new system empowers the RUHS quality department and patient safety to optimize risk-reduction strategies.

- Requested and Championed by – RUHS-MC Quality Management
- Reviewed and pre-approved by – Central Purchasing Sole Source Team

- Anticipated BOS agenda date – April 30, 2024

26520 Cactus Avenue, Moreno Valley, California 92555 | Phone: 951-486-4411

Board approval of this Agreement is required as it exceeds the authority delegated to the purchasing agent to sign agreements.

Date: 1/29/2024

From: RUHS Quality Management

To: Board of Supervisors/Purchasing Agent,

Via: Israel Gomez, Procurement Contract Specialist

Subject: Sole Source Procurement; Request for Datixweb to RL6 Platform

The below information is provided in support of my department requesting approval for a single source.

1. **Supplier being requested:** Datix (USA), Inc.

2. **Vendor ID:** 0000218200

3. ■ **Single Source** ☐ **Sole Source**

4. **Have you previously requested and received approval for a sole or single source request for this vendor for your department?** *(If yes, please provide the approved sole or single source number)*.

   ■ **Yes** ☐ **No**
   SSJ# *19-028B*

4a. **Was the request approved for a different project?**

■ **Yes** ☐ **No**

In August of 2018 the Riverside University Health System-Medical Center (RUHS-MC) entered into an agreement with Datix (USA) Inc. to use DatixWeb as the source for managing incident reports and improving patient safety. (SSJ #19-028) DatixWeb has been effective in handling the needs in which it was intended for, but the web-based reporting site is now becoming obsolete and is no longer being maintained by Datix (USA) Inc. It is because of the previously mentioned reason that RUHS-MC needs to migrate to a new system.

5. **Supply/Service being requested:**
   Datix RL6 Patient Safety, Risk Management & Quality Improvement Software Solutions

6. **Unique features of the supply/service being requested from this supplier.**
   The Datix RL6 Patient Safety, Risk Management & Quality Improvement Software Solutions offer a streamlined and objective approach for the quality management and risk department

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to governed risk event reporting and risk stratifying events that are both preventable and often associated with claims. The compliance surveillance solution will help manage accountability and safety through physician peer reviews and credentialling, as well as accreditation and regulatory requirements. Its primary goal is to enhance patient safety and drive performance improvement. With RL6 software, valuable insights will be easily accessible to all stakeholders (i.e., nurses, physicians, and other hospital staff) promoting transparency and informed decision-making, ultimately resulting in a safer and better experience patient.

Reasons why my department requires these unique features from the vendor and what benefit will accrue to the county:

To comply with regulatory standards set forth by The Joint Commission (TJC) and the centers for Medicare and Medicaid Services (CMS), all hospitals are required to maintain a confidential event reporting system along with existing voluntary reporting systems, while there are many stand-alone software solutions on the market that may be able to manage safety event reporting; however, there is not one single comprehensive systems that is integrated as one part of Patient Safety Platforms that can give insights to value of care as well as quality and effectiveness of care being delivered. Recommendations from the President's Council of Advisors On Science and Technology (PCAST, 2023)(See Attachment number I) under Recommendation number 2, summarizes what technology should be able to do (see attached documents). These same recommendations set the standards by which all regulatory agencies measure safety compliance. Riverside University Health System (RUHS) needs a patient safety software solution that goes beyond just having a software to house adverse events reported, RUHS needs a solution that can help effectively manage adverse event information to mitigate and risk-stratify preventable harm. The positive downstream effect of such a robust program can help minimize claims and litigations from ineffective processes within a system.

Three crucial advantages with this single source requisition are: (a) RUHS is currently using the old and obsolete version of the Datix system with outdated functionality. The transition will require re-mapping these functions without having to learn a new system and hiring a new analyst/IT to manage or figure out the new operating systems; (b) RL Datix provides a comprehensive solution that is aligned with the PCAST recommendations as well as leading the industry in patient safety Governance, Risk Management, Compliance and Accreditation; and (c) we currently do not have a robust risk management program that can link filed claims to preventable harms. By implementing the Datix (USA) Inc. system, it ensures compliance and enable collaborative efforts to compare and benchmark safety data. This new system empowers the RUHS quality department and patient safety to optimize risk- reduction strategies.

7. Period of Performance: From: FY23/24 to FY28/29

Is this an annually renewable contract?	■ No	☐ Yes
Is this a fixed-term agreement:	☐ No	■ Yes

8. Identify all costs for this requested purchase. In addition, please include any single or sole source amounts previously approved and related to this project and

vendor in the section designated below for current and future fiscal years. You do not need to include previous fiscal year amounts. If approval is for multiple years, ongoing costs must be identified below. If annual increases apply to ongoing costs such as CPI or other contract increases, provide the estimated annual cost for each consecutive year. If the annual increase may exceed the Purchasing Agent's authority, Board approval must be obtained.

Total contract amount for this Agreement, is $1,001,217.16

FINANCIAL DATA	Contingency	First Year	Second Year	Third Year	Fourth Year	Fifth Year	Total Cost
COST	$91,019	$220,159	$164,938.02	$169,886.16	$174,982.75	$180,232.23	$1,001,217.16

9. **Price Reasonableness:**
A proposal analysis report was run by ECRI to determine if the pricing we are receiving is fair. ECRI determined that the prices being offered to the County of Riverside are on par with what's being offered to other government agencies and healthcare facilities. (See Attachment 2)

10. **Projected Board of Supervisor Date (if applicable):** 04/30/24
(Draft Form 11s, service agreement and or quotes must accompany the sole source request for Purchasing Agent approval.)

Department Head Signature (or designee)	Print Name	Date
Jennifer J Crutchfield	Evelyn Rangel	03/21/2024

The section below is to be completed by the Purchasing Agent or designee.

Purchasing Department Comments:

Approve **Approve with Condition/s** **Disapprove**

Condition/s:

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Riverside University HEALTH SYSTEM

Not to exceed:

☐ **One-time** $_____

■ **Aggregate Amount**: $1,001,217 (NTE) over 5 year period

☐ **Annual Amount** $_____ / per fiscal year through _____(date)
(If Annual Amount Varies each FY)

FY _____: $_____
FY _____: $_____
FY _____: $_____
FY _____: $_____
FY _____: $_____

Melissa Curtis | 4/1/2024 | 24-219

Purchasing Agent | **Date** | **Approval Number** (Reference on Purchasing Documents)

Signature: Amparo Quintero (Mar 20, 2024 10:58 PDT)
Email: ampquintero@ruhealth.org

Signature: Joe Zamora (Mar 21, 2024 10:47 PDT)
Email: j.zamora@ruhealth.org

REPORT TO THE PRESIDENT
A Transformational Effort on Patient Safety

Executive Office of the President

President's Council of Advisors on Science and Technology

September 2023

About the President's Council of Advisors on Science and Technology

The President's Council of Advisors on Science and Technology (PCAST) is a federal advisory committee appointed by the President to augment the science and technology advice available to him from inside the White House and from the federal agencies. PCAST is comprised of 28 of the Nation's thought leaders, selected for their distinguished service and accomplishments in academia, government, and the private sector. PCAST advises the President on matters involving science, technology, and innovation policy, as well as on matters involving scientific and technological information that is needed to inform policy affecting the economy, worker empowerment, education, energy, the environment, public health, national and homeland security, racial equity, and other topics.

For more information about PCAST see www.whitehouse.gov/pcast.

EXECUTIVE OFFICE OF THE PRESIDENT
PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY
WASHINGTON, D.C. 20502

President Joseph R. Biden, Jr.
The White House
Washington, D.C.

Dear Mr. President,

Doctors, nurses, and other healthcare staff are passionate, dedicated professionals who care deeply for the patients in their care. Nonetheless, dangerous and preventable events continue to occur at surprisingly high rates. According to recent data, in the United States, Medicare patients suffer an adverse event in one out of four hospitalizations. One third of those adverse events are serious, including catastrophic outcomes.[1] Consistent with observations noted in other areas of health care, adverse outcomes disproportionately impact people from groups historically experiencing social marginalization, widening gaps in healthcare disparities.[2]

Concern about errors is not new, yet progress in addressing our rates of adverse health outcomes has been unacceptably slow.[3] Not all harm is preventable; however, significant progress has been made in understanding and developing evidence-based practices to address the root causes of many categories of avoidable adverse outcomes. While there is great potential for near-term research and innovation to boost patient safety, widespread implementation of today's evidence-based solutions will significantly reduce harms.

Given your passion for patient safety and deep respect for healthcare professionals, we believe you can bring strong federal leadership to a nationwide transformational initiative to support all hospitals and practitioners with implementing evidence-based solutions and accelerating efforts to better understand and address broader challenges with patient safety, including the harnessing of advances in computing technologies to boost patient safety. The goal is to move our healthcare systems expeditiously towards zero preventable harms, so that every American receives dignified and safe care.

Per your request, the following report contains our recommendations aimed at dramatically improving patient safety in our country for all Americans.

Sincerely,
Your President's Council of Advisors on Science and Technology

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[1] Department of Health and Human Services (HHS). (2022 May 9). Adverse Events in Hospitals: A Quarter of Medicare Patients Experiences Harm in October 2018. *Office of Inspector General (OIG),* OEI-06-18-00400. https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf

[2] Agency for Healthcare Research and Quality. (2022 October). 2022 National Healthcare Quality and Disparities Report. Rockville, MD. AHRQ Pub. No. 22(23)-0030. https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2022qdr.pdf

[3] Bates, D. W., & Singh, H. (2018 November). Two Decades Since *To Err Is Human*: An Assessment Of Progress And Emerging Priorities In Patient Safety. *Health Affairs,* 37(11): 1736-1743. https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.0738

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Working Group on Patient Safety

Working Group members participated in the preparation of this report. The full membership of PCAST reviewed and approved the report.

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University Hospitals Cleveland Medical
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Founding Member
Patients for Patient Safety

** Denotes PCAST member*

Executive Summary

Patient safety is an urgent national public health issue. According to recent data, approximately one in four Medicare patients experience adverse events during their hospitalizations, with many resulting in catastrophic outcomes. More than 40 percent of these events are determined to be due to preventable errors.[4] Efforts to address this urgent problem are underway across federal agencies, but more must be done. This report seeks to empower existing and new efforts that will transform patient safety.

Harm from unsafe care occurs in all healthcare settings and affects all persons, from mothers and babies to seniors. Moreover, adverse outcomes of unsafe care disproportionately impact people experiencing social marginalization due to race, ethnicity, sexual orientation, gender identity, income, education, socioeconomic status, or physical and mental ability, resulting in health disparities.[5] Examples of harms include, but are not limited to, medication errors, hospital-associated infections, surgical injuries, diagnostic errors and delays, medical device malfunctions, and "failure to rescue," which is a failure to recognize and respond adequately to physiologic events that can cascade to death.

People enter the challenging and rewarding professions of healthcare because they are passionate about helping individuals to live healthy and fulfilling lives through delivering the best care possible. The organizations in which they work—hospitals, outpatient clinics, and small-practice offices, among others—are also committed to deliver lifesaving care every day. Despite commitments to quality care by practitioners and their organizations, alarmingly high rates of medical errors and patient injuries persist. There is much left to learn about how to make healthcare safer, but over the last two decades, progress has been made in understanding root causes of avoidable medical errors and evidence-based solutions have been developed to reduce many forms of injury. For example, evidence-based solutions have been developed for minimizing hospital-associated infections, pressure ulcers, medication errors, and surgical mishaps. Safety-enhancing protocols extend to "systems level" practices such as methods for boosting situational awareness that reduce errors due to discontinuities in care that occur during handoffs at changes of shifts of care teams[6] and also with transitions of patients between care organizations.[7]

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[4] Department of Health and Human Services (HHS). (2022 May 9). Adverse Events in Hospitals: A Quarter of Medicare Patients Experiences Harm in October 2018. *Office of Inspector General (OIG),* OEI-06-18-00400. https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf

[5] Piccardi, C., Detollenaere, J., Vanden Bussche, P. & Willems S. (2018 August 7). Social disparities in patient safety in primary care: a systematic review. *International Journal for Equity in Health,* 17: No. 114. https://equityhealthj.biomedcentral.com/articles/10.1186/s12939-018-0828-7

[6] Blazin, L.J., Sitthi-Amorn, J., Hoffman, J.M., & Burlison, J.D. (2020 July/August). Improving Patient Handoffs and Transitions through Adaptation and Implementation of I-PASS Across Multiple Handoff Settings. *Pediatric Quality and Safety,* 5(4): e323. https://journals.lww.com/pqs/Fulltext/2020/07000/Improving_Patient_Handoffs_and_Transitions_through.21.aspx

[7] Earl, T., Katapodis, N., Schneiderman, S., Care Transitions. In: Hall, K.K., Shoemaker-Hunt, S., Hoffman, L., et al. (2020 March). Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices [Internet]. *Agency for Healthcare Research and Quality*, Report No.: 20-0029-EF. https://www.ncbi.nlm.nih.gov/books/NBK555516/

Despite significant efforts made by dedicated health professionals, agencies, and organizations, uniform, nationwide implementation of many of these known solutions has lagged.[8] The Biden-Harris administration has already taken key steps to improve the quality of healthcare for every American. Now is the right time to renew our nation's commitment to improving patient safety. Parallel to improvement of patient safety is the additional and closely linked aim of improving safety for the healthcare workforce. An additional benefit of widespread patient safety improvement will be substantial reductions in the total cost of healthcare in America.

All of this will become far more likely with strong and committed federal leadership to: (a) create a nationwide transformational initiative to support every hospital and practitioner in implementing known safety solutions for both patients and the workforce and sustaining them over time; and (b) create and maintain a robust national enterprise aimed at accelerating research, development, and deployment of technology and policies aimed at improving patient safety. The Biden-Harris administration can take bold action to advance health equity, improve the nation's health and well-being, and avert suffering and death for hundreds of thousands of Americans each year.

Recommendations

Recommendation 1: Establish and Maintain Federal Leadership for the Improvement of Patient Safety as a National Priority.

The President should bring immediate attention to the urgent need to improve patient safety and healthcare workforce safety as a national priority, by establishing a *White House-led Transformational Effort on Patient Safety.* The *initiative* should commit to taking significant and tangible steps forward to solve the critical challenges with patient safety in the public and private sectors, and direct the Department of Health and Human Services (HHS) Secretary to oversee coordination across HHS agencies including accountability for progress, with public reporting to the President at least annually.

1.A Appoint a Patient Safety Coordinator Reporting to the President on Efforts to Transform Patient Safety Among All Relevant Government Agencies.

1.B Establish a Multidisciplinary National Patient Safety Team (NPST) and Ensure Inclusion of Persons from Populations Most Affected.

Recommendation 2: Ensure That Patients Receive Evidence-Based Practices for Preventing Harm and Addressing Risks.

The President should direct the HHS Secretary, in collaboration with the Department of Defense (DoD), and Department of Veterans Affairs (VA), to require the appropriate federal agencies to develop a list of high-priority harms, evidence-based practices, and system-level mitigation strategies to eliminate preventable harms, including "never events" that should never occur in healthcare. As many measures as possible should be generated from real-time automated electronic health data.

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[8] Bates, D. W., & Singh, H. (2018 November). Two Decades Since *To Err Is Human*: An Assessment Of Progress And Emerging Priorities In Patient Safety. *Health Affairs,* 37(11): 1736-1743. https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.0738

2.A Identify and Address High-Priority Harms and Promote Patient Safety Though Incentivizing the Adoption of Evidence-Based Solutions and Requiring Annual Public Reporting Immediately and Quarterly Public Reporting Within 5 Years.

2.B Create a Learning Ecosystem and Shared Accountability System to Ensure That Evidence-Based Practices are Implemented and Goals for Reduced Harms and Risks of Harm for Every American are Realized.

2.C Advance Interoperability of Healthcare Data and Assure Access to the Tracking of Harms and Use of Evidence-Based Solutions.

2.D Improve Safety for All Healthcare Workers and Their Patients Through Supporting a Just Culture of Patient and Clinician Safety in Healthcare Systems.

Recommendation 3: Partner with Patients and Reduce Disparities in Medical Errors and Adverse Outcomes.

It is crucial to engage diverse stakeholders in the nation's efforts to reduce the risk of harm from unsafe care. This should include partnering and collaborating with patients, families, and communities disproportionately impacted by unsafe care. Implementing evidence-based solutions in healthcare settings should include patient-centered approaches and give special attention to long-standing disparities. To address disparities in patient safety, the President should direct the following activities:

3.A Implement a "Whole of Society Approach" in the Transformational Effort on Patient Safety.

3.B Improve Data and Transparency to Reduce Disparities.

Recommendation 4: Accelerate Research and Deployment of Practices, Technologies, and Exemplar Systems of Safe Care.

Beyond today's knowledge, it is critically important to accelerate the development and deployment of new technologies, processes, and evidentiary foundations for safe healthcare, so that errors and injuries are minimized. Promising directions include harnessing new practices and technologies for assisting with medication selection and management, improving accuracy of diagnosis, shortening time to diagnosis, monitoring, as well as predictions about treatment effectiveness based on individual characteristics.

4.A Develop a National Patient Safety Research Agenda.

4.B Harness Revolutionary Advances in Information Technologies.

4.C. Develop Federal Healthcare Delivery Systems' Capacities and Showcase Results as Exemplars for Safer Healthcare.

A Transformational Effort on Patient Safety

Introduction

Patient safety is an urgent national public health issue. Considerable efforts have been undertaken across the US healthcare system to address the complex challenges that lead to unsafe care and, in too many cases, catastrophic outcomes.[9]

When Americans seek medical care, they trust that the health system and its clinicians will deliver safe, dignified, and effective care. Delivering high-quality, equitable healthcare is a complex endeavor. For example, in a hospital setting there are a range of critical factors that play a role in the care a patient receives and in their health outcome, with clinicians, practices and procedures, technology, medicines, physical infrastructure, and patients and their family members all playing important roles. The nature of and inter-relationships among these factors can influence the quality of care and likelihood of adverse outcomes.

Avoidable medical errors can occur at various points over the course of the patient experience, some resulting in severe, life-changing harms to the patient. This unacceptable situation continues to disproportionately impact people experiencing marginalization. The Biden-Harris administration has taken key steps to improve the quality of healthcare and access to healthcare for every American, which makes now a ripe time to renew our focus and commitment to improving patient safety.

A report by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) found that nearly 25 percent of Medicare beneficiaries were harmed during hospital stays during October 2018 and that more than 40 percent of those harm events could have been prevented with better care.[10] More recently, a January 2023 article similarly reported that adverse events occurred in nearly one in four hospital admissions based on data collected from January to December 2018. One-third of those adverse events were serious, and one-fourth of the adverse events were preventable.[11] The authors of the study also noted that there is substantial undercounting of adverse events in U.S. hospitals due to reliance on voluntary reporting. They assert that measuring adverse events in a reliable and efficient way would be necessary to build understanding on the path to preventing these events. Taken together, these studies demonstrate that medical errors and resulting patient harms persist and many remain undetected, obfuscating the depth of the challenge and making learnings and improvement challenging.

Significant morbidity and mortality stems from misdiagnosis and inappropriate delays in care, including harmful delays in converging on diagnoses and delivering needed therapy after patients

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[9] Bates, D. W., & Singh, H. (2018 November). Two Decades Since To Err Is Human: An Assessment Of Progress And Emerging Priorities In Patient Safety. *Health Affairs*, 37(11): 1736-1743. https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.0738

[10] Department of Health and Human Services (HHS). (2022 May 9). Adverse Events in Hospitals: A Quarter of Medicare Patients Experiences Harm in October 2018. *Office of Inspector General (OIG),* OEI-06-18-00400. https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf

[11] Bates, D.W., Levine, D.M., Salmasian H. et al. (2023 January 12). The Safety of Inpatient Health Care. *New England Journal of Medicine (NEJM),* 388: 142-153. https://www.nejm.org/doi/full/10.1056/NEJMsa2206117

first engage with the medical system.[12, 13, 14, 15] Delays in diagnosis and treatment have further been linked to socioeconomic disparities.[16, 17]

A National Academies report released in 2015 estimated that errors in diagnosis contribute to approximately 10 percent of patient deaths and account for six to 17 percent of hospital adverse events.[18] The report included data from a 2018 report estimating that over 12 million Americans[19] are impacted by diagnostic error each year and that the cost of diagnostic errors to the U.S. healthcare system may be over $100 billion annually.[20] A national survey in 2017 revealed that diagnostic errors were the most commonly reported type of medical error experienced by patients, accounting for 60 percent of all medical errors.[21] A December 2022 Agency for Healthcare Research and Quality's (AHRQ) study found that nearly 6 percent of patients coming to emergency departments receive incorrect diagnoses and 2 percent result in adverse events, leading to an estimated 7.4 million

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[12] Sterling, S.A., Miller, W.R., Pryor, J., Puskarich, M.A., & Jones, A.E. (2015 September 1). The Impact of Timing of Antibiotics on Outcomes in Severe Sepsis and Septic Shock: A Systematic Review and Meta-Analysis. *Critical Care Medicine,* 43(9): 1907-1915. https://journals.lww.com/ccmjournal/Abstract/2015/09000/The_Impact_of_Timing_of_Antibiotics_on_Outcomes_in.16.aspx

[13] Sekoranja, L., Griesser, A.C., Wagner, G., et al. (2009 July 11). Factors influencing emergency delays in acute stroke management. *Swiss Medical Weekly (SMW),* 139(27-28):393-9. https://smw.ch/index.php/smw/article/view/993/990

[14] Alrawashdeh, A., Nehme, Z., Williams, B., Smith, K., Brennan, A., Dinh, D.T., Liew, D., Lefkovits, J., & Stub, D. (2021 April 16). Impact of emergency medical service delays on time to reperfusion and mortality in STEMI. *Open Heart,* 8(1): e001654. https://openheart.bmj.com/content/openhrt/8/1/e001654.full.pdf

[15] De Luca, G., Suryapranata, H., Ottervanger, J.P., & Antman, E.M. (2004 March 4). Time delay to treatment and mortality in primary angioplasty for acute myocardial infarction: every minute of delay counts. *Circulation,* 109(10): 1223-5. https://www.ahajournals.org/doi/epub/10.1161/01.CIR.0000121424.76486.20

[16] Miller, A.L., Simon, D., Roe, M.T., Kontos, M.C., Diercks, D., Amsterdam, E., & Bhatt, D.L. (2017 April 15). Comparison of Delay Times from Symptom Onset to Medical Contact in Blacks Versus Whites with Acute Myocardial Infarction. *The American Journal of Cardiology,* 119(8): 1127-34. https://www.sciencedirect.com/science/article/abs/pii/S0002914917300395?via%3Dihub

[17] Lim, B., Chauhan, D., Schultz, M.L., Levine, D., Loumiotis, I., Friedmann, P., Parides, M.K., Forest, S.J., DeRose, J.J. (2022 March 5). Relation of Community-Level Socioeconomic Status to Delayed Diagnosis of Acute Type A Aortic Dissection. *The American Journal of Cardiology,* 170: 147-54. https://www.sciencedirect.com/science/article/abs/pii/S000291492200090X?via%3Dihub

[18] National Academies of Sciences, Engineering, and Medicine, Institute of Medicine. (2015 September). Improving Diagnosis in Health Care. *Washington, DC: National Academies Press (NAP).* https://nap.nationalacademies.org/catalog/21794/improving-diagnosis-in-health-care

[19] Singh, H., Meyer, AND., & Thomas, EJ. (2014 August 12). The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. *BMJ Quality & Safety,* 23: 727-731. https://qualitysafety.bmj.com/content/23/9/727

[20] Society to Improve Diagnosis in Medicine (SIDM), & Coalition to Improve Diagnosis (CID) Policy Committee. (2018 February 7). The Roadmap for Research to Improve Diagnosis, Part 1: Converting National Academy of Medicine Recommendations into Policy Action. *SIDM Policy Roadmap for Research to Improve Diagnosis.* https://www.improvediagnosis.org/wp-content/uploads/2018/10/policy_roadmap_for_diagnosti.pdf

[21] NORC at the University of Chicago & Institute for Healthcare Improvement National Patient Safety Foundation (IHI/NPSF) Lucian Leape Institute. (2017 September 28). Americans' Experiences with Medical Errors and Views on Patient Safety. *Cambridge, MA: Institute for Healthcare Improvement and NORC at the University of Chicago.* https://www.ihi.org/about/news/Documents/IHI_NPSF_NORC_Patient_Safety_Survey_2017_Final_Report.pdf

misdiagnoses and 2.6 million adverse events per year in the U.S.[22] A July 2023 study reported that over 500,000 Americans are permanently disabled or die per year because of misdiagnosis and that misdiagnoses of 15 diseases account for about 50 percent of all serious harms, and nearly 40 percent are accounted for by the top five conditions, including stroke, sepsis, pneumonia, venous thromboembolism, and lung cancer.[23] Although findings vary across studies, many of these reports have documented disparities in harms experienced by patient based on age, sex, gender, race, and ethnicity.[24]

Leadership Needed Now for Dramatic Improvements in Patient Safety

Fortunately, over the last two decades progress has been made in understanding the root causes of many types of medical errors, and tested or evidence-based solutions have been developed to address these challenges. We now need federal government leadership to create a nationwide transformational initiative on patient safety to support every hospital and practitioner with implementing these solutions and sustaining them over time. In addition, we need federal leadership to further advance the scientific knowledge base for healthcare safety so that errors and injuries considered unavoidable today become preventable in the future.

It should be the policy of the Biden-Harris Administration, through both federal action and public-private partnership, to immediately, dramatically, measurably, and continually reduce healthcare-associated injuries to patients and workplace injuries to the healthcare workforce. Healthcare professionals grapple with the risk of physical harm,[25, 26] such as exposure to infectious disease, musculoskeletal injuries, and violence,[27] and mental health challenges,[28] including exhaustion, sleep deprivation, and burnout.[29] All proposed actions must incorporate and empower the voices and

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[22] Newman-Toker, D.E., Peterson, S.M., Badihian, S. et al. (2022 December 15). Diagnostic Errors in the Emergency Department: A Systematic Review No. 258. Comparative Effectiveness Review. *Rockville, MD: Agency for Healthcare Research and Quality (AHQR), Effective Health Care Program,* No. 22(23)-EHC043. https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/cer-258-diagnostic-errors-research.pdf

[23]Newman-Toker, D.E., Nassery, N., Schaffer, A.C., et al. (2023 July 17). Burden of serious harms from diagnostic error in the USA. *BMJ Quality & Safety.* https://qualitysafety.bmj.com/content/early/2023/07/16/bmjqs-2021-014130

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[27] Odes, R., Lee, S.J., Hong, O., & Jun, J. (2023 February 10). The effect of COVID-19 on workplace violence in California's hospitals: An interrupted time series analysis. *Journal of Advanced Nursing,* 79(6):2337-2347. https://onlinelibrary.wiley.com/doi/10.1111/jan.15588

[28] Murray, E., Kaufman, K.R., & Williams, R. (2021 August 19) Let us do better: learning lessons for recovery of healthcare professionals during and after COVID-19. *BJPsych Open,* 7(5): e151. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8376907/#

[29] Kelley, M.M., Zadvinskis, I.M., Miller, P.S., Monturo, C., Norful, A.A., O'Mathúna, D., Roberts, H., Smith, J., Tucker, S., Zellefrow, C., & Chipps, E. (2022 August). United States nurses' experiences during the COVID-19

participation of patients, families, communities experiencing marginalization, and community-based organizations to leverage their lived experience and expertise to influence patient safety policy and practice to be more patient-centered.

Recommendation 1: Establish and Maintain Federal Leadership for the Improvement of Patient Safety as a National Priority.

Through public statements and a series of linked Executive Orders, the President should bring immediate and sustained attention to the urgent need to reduce harm to patients from unsafe care and improve healthcare workforce safety as a national priority. The President should establish a **White House-led *Transformational Effort on Patient Safety***, that commits to more comprehensively engage all relevant government agencies to help solve the critical challenges in both the public and private sectors.

This transformational effort should include both immediate actions to address the crisis and actions that ensure lasting change, recognizing that incremental change has not been adequate and a radical redirection of approach is required.

The President should immediately establish clear leadership, with lines of accountability across HHS for long-term and lasting success over a horizon of 10 years, aimed at making healthcare safer by minimizing injuries to patients and healthcare workers and reducing disparities in patient safety, dramatically, measurably, and sustainably by 2030. The transformational effort should focus on leveraging knowledge about safety science, human factors, advances in information technology, including data analytics and fast-paced developments in AI, and via establishing new forms of participatory engagement with patients and their families. The President should call on the nation to work collaboratively and urgently to prioritize and vastly improve safety. This work should engage patients, family members, community organizations, and healthcare professionals and organizations, all while prioritizing the reduction of inequities and disparities in healthcare delivery and health outcomes.

Recommendation 1.A

Appoint a Patient Safety Coordinator, Reporting to the President, on Efforts to Transform Patient Safety Among All Relevant Government Agencies.

The President should create a new Patient Safety Coordinator role in the White House, reporting directly to the President, to help coordinate effective patient safety improvement efforts at the federal level, as well as engaging with non-government stakeholders. The Patient Safety Coordinator will work closely with the Secretary of HHS, who will remain the leader for implementation of patient safety, enhancing systems and structures at HHS to facilitate long-term impact. The Patient Safety Coordinator will work with the Secretary of HHS to convene federal agency leadership on a regular basis, including working with the Office of Management and Budget (OMB) to identify resources and funding for these activities, and engaging with critical stakeholder groups including hospitals, clinicians, patient groups, and more, to help support implementation of these recommendations.

Reflecting a "whole-of-government" approach, the Patient Safety Coordinator should convene and oversee coordination of patient safety initiatives across federal agencies and regularly account for progress through public reporting to the President. The coordination strategies should align with and

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pandemic: A grounded theory. *Journal of Clinical Nursing,* 31(15-16):2167-2180. https://onlinelibrary.wiley.com/doi/10.1111/jocn.16032

further efforts on addressing disparities in patient safety, directing the allocation of resources, and specifying the goals and timeline for implementing this bold patient safety agenda.

The President should charge the HHS, DoD, DoJ, and VA Secretaries with providing a timeline and specific goals for improving patient safety outcomes, based on the high-priority-harms (see Recommendation 2.A), including working with the White House Patient Safety Coordinator to deliver at least annual reporting to the President on the progress in improving patient safety and implementation of (recommended or specific) actions. The public annual report will also be published, similar to the transportation safety national reports, detailing progress toward eliminating harms identified as highest priority.

Box 1: A coordinated federal effort should include special focus advisory groups:

Patient and family group to ensure regular and formal input from a diverse set of patient, family, and community voices, especially those from groups who have experienced harm from unsafe care.

Healthcare workforce group (representing physicians, nurses, technicians, pharmacists, and other healthcare professionals), to ensure appropriate input from the healthcare workforce and to ensure that any new recommendations work to prevent and reduce unnecessary administrative or regulatory burdens that are placed on health workers, and to optimize the use of technologies that support health workers, while minimizing technologies that inhibit clinical decision-making.

Safety science group comprised of highly qualified experts in safety science and human factors engineering, drawn from healthcare and other high-hazard industries, healthcare equipment manufacturers, healthcare legal experts, and technology experts in the field of bioinformatics, AI, medical device safety, and health economics.

*All teams should include people with a diversity of lived experiences and people with expertise in structural and social determinants of health.

Recommendation 1.B

Establish a Multidisciplinary National Patient Safety Team, Including Those Most Affected.

The President should direct the Secretary of HHS to establish a dedicated, independent, healthcare safety investigation body, the *National Patient Safety Team* (NPST). The NPST should examine and analyze safety issues and opportunities for mitigating and addressing safety challenges with healthcare delivery independently, issuing non-punitive, non-binding, and learning-focused safety recommendations that support system-wide improvements.

The NPST should compose and operate a public-private partnership team, similar to the Commercial Aviation Safety Team (CAST),[30] comprised of multidisciplinary clinical, informatics, technology/AI, data science, safety science, and human-factors experts, and go one step further to include insights from patients and families.

[30] The Commercial Aviation Safety Team (CAST). (1997). https://www.cast-safety.org/apex/f?p=102:1

The NPST should fully engage to gain an understanding of perspectives of clinicians and of patients and families. Thorough engagement will require that the NPST take steps to specifically ensure that patients and families, as well as health professionals, especially those belonging to groups that experience the most social and economic marginalization, are represented. Non-punitive protections should be included for healthcare professionals and others who provide information to the NPST.

The NPST should focus on system-level solutions including, but not limited to, threat and error management (e.g., eliminating confusing names, labels and containers for medications where errors can be catastrophic), eliminating potential single-point failures, leveraging lessons from human factors to improve the safety of healthcare facilities, devices and systems, addressing team communication and collaboration failures, and including opportunities for the effective and responsible use of AI technologies.

The NPST should make recommendations to AHRQ to develop patient safety reporting and learning systems for patients, families, and clinicians to report experiences or observances of harm. These systems must be independent from the organization where harm may have occurred, should empower learning, be non-punitive and ideally be part of the regular public reporting by the White House Patient Safety Coordinator recommended in 2.A. Any data collected should enable disparity stratification efforts by race, ethnicity, primary language, and other socio-demographics, when possible. The NPST's recommendations should be made public. While non-binding, federal and state agencies that accredit healthcare organizations should consider using the NPST's recommendations in their assessments.

Determining the Scope of the Problem

The federal government should establish a robust and transparent mechanism to quantify the degree of harms in the U.S. healthcare system overall, including for the most vulnerable populations, and to monitor progress in reducing harm. Transformational improvement of patient safety requires ensuring more effective use of incident reporting at the national and local levels and supplementing these data with other ways to measure adverse outcomes as well as threats to patient safety including enhanced monitoring for adverse events via signals from electronic health record systems and medical devices and predictive analytics to assess the risk of harms. The federal government will need multiple ways to assess and prevent the root causes of harms, including understanding of rates of adverse outcomes and how they differ by demographic groups.

Numerous methods can be employed to measure harms to patients and, unfortunately, these methods often present conflicting inferences about the magnitude of the problem and progress in mitigating harm. Quantifying the scope and severity of medical errors is challenging and recent studies note that the true rate of harms may be underestimated due to underreporting.[31] The US can, and should, develop better measures for major causes of harm, and threats of harm, for a larger set of causes of harms. Today such measures of threats are derived from incident reports, although these are not adequately standardized, are prone to bias, and under-report harms especially in populations

[31] Shojania, K.G. & Dixon-Woods, M. (2017 April 18). Estimating deaths due to medical error: the ongoing controversy and why it matters. *BMJ Quality & Safety,* 26: 423-28. https://qualitysafety.bmj.com/content/26/5/423

that are socially marginalized.[32, 33] There is concern that the health systems that put patients at greatest risk for unsafe care often report the least, paradoxically making them appear safer.

Recommendation 2: Ensure That Patients Receive Evidence-Based Practices for Preventing Harm and Addressing Risks.

Researchers and practitioners in healthcare have made substantial progress over the past two decades in learning how to reduce many forms of medical error and patient injuries. Specific interventions have been identified and demonstrated to be effective, including, among others, using checklists (such as in operating rooms before surgery), standardizing procedures reliably to conform to the best science (such as correctly managing respirator machines, intravenous catheters, and urinary catheters), communicating structured information about patients to enhance situation awareness when care teams transition (reporting on illness severity, action lists, and contingency plans, etc.), and creating "just cultures" in which all staff and patients feel safe and supported to report hazards and errors that they observe. Some hospitals have driven to nearly zero significant hospital-associated infections, pressure ulcers, and certain types of surgical mishaps for extended periods of time.

Unfortunately, progress on patient safety too often remains spotty and local, rather than permeating the American health system. As a result, far too many patients do not benefit from these evidence-based practices. It is time to create and act on a guarantee: that every American will experience care that corresponds to the leading safety practices. This can and should begin with a national focus on high-priority conditions for which mitigations have been developed, then designing incentives and supports for all hospitals and healthcare settings to achieve gains that have been demonstrated elsewhere. At the same time, we need to double down as a nation on pushing on the science and technology to develop new understanding, practices, and technologies to address adverse outcomes more broadly, including those that do not yet have satisfactory mitigations.

Healthcare is unique among high-risk industries in not fully measuring or understanding the magnitude of harms, not substantively mitigating recognized harms, and not ensuring transparency and shared accountability for making progress. To remedy this, the healthcare ecosystem must move toward more effective learning and deeper accountability on patient safety. We recommend that the White House Patient Safety Coordinator work with HHS to facilitate the creation of an ecosystem that learns and is accountable to materially reducing harms and threats of harm for every American. Such an ecosystem would be inclusive, involve diverse stakeholders including those suffering harms, healthcare delivery organizations, technology companies, professional organizations, and regulators.

Recommendation 2.A

Identify and Address High-Priority Harms and Promote Patient Safety Though Incentivizing the Adoption of Evidence-Based Solutions and Requiring Annual Public Reporting Immediately with an Aspiration of More Frequent Reporting in the Future.

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[32] McDonald, C.J., Weiner, M. & Hui, S.L. (2000 July 5). Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report. *Journal of the American Medical Association (JAMA),* 284(1): 93-95. https://jamanetwork.com/journals/jama/fullarticle/192843

[33] Brennan, T.A. (2000 April 13). The Institute of Medicine Report on Medical Errors — Could It Do Harm?. *New England Journal of Medicine (NEJM),* 342:1123-25. https://www.nejm.org/doi/10.1056/NEJM200004133421510?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

The President should direct the HHS Secretary, in collaboration with the DoD, VA and DoJ where relevant to require the appropriate federal agencies to develop a list of high-priority harms, as well as evidence-based practices and system-level mitigation strategies to eliminate those harms. This will require more effective and widely used measures of harms, with as many measures as possible generated from real-time automated electronic health data. A list of high-priority harms should likely include, but not be limited to, medication adverse outcomes, surgical adverse outcomes, diagnostic errors, hospital-associated infections, falls, pressure injuries, deep vein thrombosis and pulmonary embolus, and failure to rescue. Tracked and publicly reported events should include particularly serious avoidable events, referred to as "never events"—adverse events and outcomes that should never occur in healthcare. Such events include sets of surgical or procedural events, product or device events, patient protection events, care management events, environmental events, radiologic events, and criminal events.[34, 35, 36, 37] HHS should prioritize efforts, such as those currently being implemented by the Agency for Healthcare Research and Quality,[38] to identify and dedicate resources to support those hospitals which serve populations disproportionately affected by harms.

The Secretary of HHS should require that the Centers for Medicare and Medicaid Services (CMS) develop, implement, and continually evaluate mechanisms to incentivize hospitals to employ evidence-based patient safety solutions, especially those directed at the identified high-priority harms. Incentives and penalties should include organizations not being reimbursed for the primary and harm-associated care if evidence-based practices are not in place. Conversely, if the evidence-based patient safety solutions are in place and the patient is harmed, the hospital should be reimbursed for not only the primary care, but also the harm-associated care. Other approaches to incentivizing patient safety include employing an expanded list of adverse events tracked in the Hospital-Acquired Conditions program for payment reductions.[39] Incentives should specifically reward excellent quality and safety performance for underserved populations, and HHS should provide additional support to hospitals that lack adequate resources such as safety-net hospitals and those serving disproportionately affected populations.

Financial penalties have the potential to exacerbate disparities along race and class lines and across hospitals; therefore, the impact of these incentives and penalties on safety-net and other hospitals caring for populations with greater medical and/or social needs should be closely monitored to avoid unintended consequences. Additionally, consideration should be given to incentivizing hospitals engaged in efforts to expand access to underserved populations and/or to reduce disparities in

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[34] Serious Reportable Events in Healthcare: A Consensus Report. (2002). Washington, DC. *National Quality Forum*. Summary: https://www.qualityforum.org/projects/hacs_and_sres.aspx#t=1&s=&p= Accessed: August 2023.

[35] Kizer, K.W. & Stegun, M. B. (2005 February). Serious Reportable Adverse Events in Health Care. Henriksen, K., Battles, J.B., Marks, E.S., Lewin, D.I. (eds). *Advances in Patient Safety: From Research to Implementation (Vol. 4: Programs, Tools, and Products).*

[36] Serious Reportable Events in Healthcare 2011. (2011 December) *National Quality Forum.* https://www.qualityforum.org/Publications/2011/12/Serious_Reportable_Events_in_Healthcare_2011.aspx

[37] Never Events. (2019 September 7). *Patient Safety Network, Agency for Healthcare Research and Quality*. https://psnet.ahrq.gov/primer/never-events, Accessed: August 2023.

[38] Patient Safety and Quality Improvement. *Agency for Healthcare Research and Quality.* https://www.ahrq.gov/patient-safety/index.html Accessed August 2023

[39] Waters, T. M., Daniels, M. J., Bazzoli, G. J., et al. Effect of Medicare's Nonpayment for Hospital-Acquired Conditions: Lessons for Future Policy. (2015 March). *JAMA Intern Med. 2015;175(3):347-354.* https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2087876

care.[40] CMS should also require mandatory and public reporting (at least annually and moving to more frequently) of high-priority harms by individual healthcare organizations (not aggregated systems). CMS should use the list of high-priority harms and associated evidence-based solutions to inform its pay for performance program. While positive incentives may be more desirable than penalties, strong tools, such as Condition of Participation (CoP), may be necessary to accelerate adoption of timely reporting.

Regular reporting will help ensure accountability, and public reporting ensures transparency with the public that is served. The goal is for reporting to be rapid enough that solutions can be implemented as problems develop but also an accurate reflection of the safety status of hospitals. Annual reporting should become more frequent as reporting systems improve and automated reporting grows.

Recommendation 2.B

Create a Learning Ecosystem and Shared Accountability System to Ensure That Evidence-Based Practices are Implemented and Goals for Reduced Harms and Risks of Harm for Every American are Realized.

The pain of the families and communities of those who have experienced harm from unsafe care is magnified when personal and system-wide accountability and transparency are lacking, and when solutions to prevent harms are not implemented. To increase board and executive accountability for safety and quality oversight, CMS should add metrics and perform surveys that relate to healthcare organizations' executive leadership and board accountability for patient safety, expanding similar tools like AHRQ's Survey on Patient Safety Culture.[41, 42] To ensure standards for timely communication to patients and families of harm events and immediate root cause analysis of the harm - with dissemination of the findings internally and with appropriate medical bodies, CMS should require within five years that hospitals demonstrate their efforts to communicate with families and appropriate medical bodies after future adverse events as a Condition of Participation. Hospitals should consider, as a model, prior efforts aimed at communication and resolution, including the Communication and Optimal Resolution Program (CANDOR)[43] and Communication Resolution Program (CRP)[44, 45, 46]

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[40] Shakir, M., Armstrong, K., & Wasfy, J.H. (2018 April). Could Pay-for-Performance Worsen Health Disparities? *J Gen Intern Med*. *2018 Apr;33(4):567-569*. https://pubmed.ncbi.nlm.nih.gov/29302881/

[41] Agency for Healthcare Research and Quality (AHRQ). Surveys on Patient Safety Culture. https://www.ahrq.gov/sops/index.html

[42] Agency for Healthcare Research and Quality (AHRQ). AHRQ's Making Healthcare Safer Reports: Shaping Patient Safety Efforts in the 21st Century. https://www.ahrq.gov/research/findings/making-healthcare-safer/index.html

[43] Agency for Healthcare Research and Quality (AHRQ). Communication and Optimal Resolution (CANDOR). https://www.ahrq.gov/patient-safety/settings/hospital/candor/index.html

[44] Mello, M.M., Boothman, R.C., McDonald, T., Driver, J. Lembitz, A., Bouwmeester, D., Dunlap, B., & Gallagher, T. (2014 January 1). *Health Affairs,* 33: No. 1 https://www.healthaffairs.org/doi/10.1377/hlthaff.2013.0828?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[45] University of Washington Medicine. Communication & Resolution Programs. *The Collaborative for Accountability and Improvement: A Program of UW Medicine.* https://communicationandresolution.org/communication-and-resolution-programs/

[46] American Medical Association (AMA). (2017). Communication and resolution programs. *AMA Advocacy Resource Center.* https://www.ama-assn.org/system/files/2019-01/ama-issue-brief-communication-and-resolution-programs.pdf.pdf

We note that CMS has stated a condition of participation (CoP) that references the important role of boards in an institution's quality assessment and performance improvement (QAPI) plan. In March 2023, CMS issued guidance on this CoP, requiring hospitals to maintain and demonstrate evidence of its QAPI program for review by CMS, as part of their efforts to deliver safe, quality patient care and prevent adverse events and patient harm (42 CFR 482.21).[47,48] Given the availability of evidence-based practices and new computing tools, the boards of healthcare institutions should commit to improving health outcomes and ensure that strategies, goals, and resources are appropriately directed to that core mission. We recommend that a diverse expert panel be created to develop a roadmap for boards that defines the key strategies that should be part of all hospitals' operational plans. Boards should consider using the latest computing applications to enhance the implementation of their strategies, free up more workforce capacity, and to limit workforce burnout, while ensuring the strategies / applications have taken algorithmic biases into account.

The Patient Safety Coordinator and HHS should collaborate to develop a learning ecosystem and shared accountability system to ensure these promising strategies for hospital operations are implemented and harms are being reduced. Shared accountability means that HHS and health systems work together to realize safety goals. CMS should consider revising its CoPs to ensure that hospitals have an annual rather than every three-year survey and that the surveyors evaluate policies and practices to reduce harms, ensuring clinicians are using evidence-based solutions and new promising and proven practices. They will also review rates of top harms and require corrective action plans for those not realizing goals. In addition, surveyors will meet with the hospital board chair, CEO, and representative of patients who have been harmed to review progress in reducing rates of adverse outcomes.

The Patient Safety Coordinator should create a learning ecosystem, to ensure goals for reducing patient harms are realized and each of these components is working optimally. As part of this effort, HHS should also highlight interventions that most effectively reduce harm to marginalized populations. This ecosystem should include all relevant federal agencies, patients, and families harmed from healthcare, technology companies, states, health systems, regulators, and professional organizations. The goal of this ecosystem is to more rapidly share what is working both horizontally and vertically among the multitude of partners needed to reduce harm and to help ensure that no group gets left behind in the efforts to reduce harm.

The learning ecosystem and shared accountability system must ensure a balance between learning from harm and accountability for mitigating harm for every American. It is a blight upon the US government that, decades after knowing the scope of patient harm, the US lacks a valid monitoring and learning system that can reduce harm. With these recommendations, the Biden-Harris Administration can create an inclusive and transparent learning and accountability system that eliminates harm for everyone.

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[47]Centers for Medicare & Medicaid Services (CMS). (1996 October). Condition of participation: Quality assessment and performance improvement program 42 CFR 482.21. Code of Federal Regulations. https://www.ecfr.gov/current/title-42/section-482.21

[48] Centers for Medicare & Medicaid Services (CMS). (2023 March 9). Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program. CMS Quality, Safety & Oversight. https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-states/revision-state-operations-manual-som-hospital-appendix-interpretive-guidelines-42-cfr-48221-quality

Recommendation 2.C

Advance Interoperability of Healthcare Data and Assure Free Access to the Tracking of Harms and Use of Evidence-Based Solutions.

Steady progress toward safer care requires seamless integration of data and easy access to information by all parties, including patients, with appropriate privacy protections. Relevant federal agencies, led by the Office of the National Coordinator for Health Information Technology (ONC), should develop a comprehensive strategy to improve the interoperability of healthcare data to support improvements in patient safety and healthcare quality, including the collection of demographic data to specifically support understandings of patient safety, healthcare quality, and equity. Healthcare data should include demographic and social determinants of health (SDOH) data, to facilitate understanding of healthcare disparities in patient safety. CMS, ONC, and other relevant federal agencies should encourage all healthcare information companies and medical technology companies to allow interoperability with easy access to data feeds via standard interfaces. Also, data from devices should be available for research on patient safety when in compliance with federal regulations such as HIPAA. The federal government should consider incentives, e.g., a tax credit, for such data philanthropy.

The safety associated with the use of medical devices would be improved with better data, including tracking of devices and their performance. Mandated inclusion of Unique Device Identifiers (UDI) in claims and in Electronic Health Records would dramatically improve data availability. In addition, the FDA should consider defining a risk rating system for medical devices that provides specific guidance for devices in accordance with levels of risk and requires routine post-marketing surveillance and evaluation for those devices, especially when a new technology is being deployed clinically. It would be valuable to include in public reporting the quality and performance measures for surgeries or other procedures that involve medical devices designated as high risk.

Box 2: Example of future agency collaboration

Building upon existing work by AHRQ to collect data from Patient Safety Organizations (PSOs), HHS, DoD, and VA could establish mandatory reporting to a national repository for patient safety events data which could support access to and interoperability of healthcare data as well as enable disparity stratification efforts.

Recommendation 2.D

Improve Safety for Every Healthcare Worker Through Supporting a Just Culture of Patient Safety and Clinician Safety in Healthcare Systems.

Results in safety science and experiences to date in other industries suggest that it will be difficult to improve patient safety substantially without simultaneous attention to improving the safety of the healthcare workforce. An unsafe, insecure, or fearful workforce cannot offer safe care. The National Patient Safety Team, with input from the healthcare workforce group as described in ***Box 1***, should be tasked to identify and disseminate evidence-based, systems level solutions to keep the workforce safe from harm during the course of their work, including harms such as needle stick injury, back injury, falls, radiation, and psychological and physical burnout. In addition, the NPST should identify and encourage implementation in healthcare organizations of mechanisms and processes that promote openness, feedback, psychological safety, reporting, and, where necessary, whistleblowing

protections, for healthcare workers seeing or facing challenges with patient and workforce safety. The whistleblowing protection should also apply to hospitals that are not reporting all patient harms, or where they have not yet implemented evidence-based solutions despite stating they have.

Recognizing Disproportionate Burden on Marginalized Groups

Preventable medical errors and their downstream effects directly contribute to and exacerbate health disparities. System-wide approaches are needed to address these disparities. People experiencing marginalization are more likely to suffer harms as a result of medical errors, inadequate testing and treatment, and inaccurate diagnosis,[49, 50, 51, 52] and they may lack the resources to adequately address harms once they have occurred. Unconscious race and class biases, in particular, can shape how clinicians perceive patients and communicate with them,[53] which has the potential to negatively impact healthcare quality and patient safety.[54, 55, 56, 57] Additionally, outcomes measures

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[49] Metersky, M.L., Hunt, D.R., Kliman, R., Wang, Y., Curry, M., Verzier, N., Lyder, C.H., & Moy, E. (2011 May). Racial Disparities in the Frequency of Patient Safety Events: Results from the National Medicare Patient Safety Monitoring System. *Medical Care,* 49(5): 504–10. https://journals.lww.com/lww-medicalcare/Abstract/2011/05000/Racial_Disparities_in_the_Frequency_of_Patient.11.aspx

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[52] Bell, S.K., Dong, J., Ngo L., McGaffigan, P., Thomas, E.J., & Bourgeois, F. (2022 February 4). Diagnostic error experiences of patients and families with limited English-language health literacy or disadvantaged socioeconomic position in a cross-sectional US population-based survey. *BMJ Quality & Safety,* Published Online. https://qualitysafety.bmj.com/content/early/2022/02/03/bmjqs-2021-013937

[53] Cooper, L.A., Roter, D.L., Carson, K.A., Beach, M.C., Sabin, J.A., Greenwald, A.G., & Inui, T.S. (2012 March 15). The associations of clinicians' implicit attitudes about race with medical visit communication and patient ratings of interpersonal care. *American Journal of Public Health* 102(5): 979-87. https://pubmed.ncbi.nlm.nih.gov/22420787

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[55] Howell, E.A., Brown, H., Brumley, J., Bryant, A.S., Caughey, A.B., Cornell, A.M., Grant, J.H., Gregory, K.D., Gullo, S.M., Kozhimannil, K.B., Mhyre J.M., Toledo, P., D'Oria R., Ngoh, M., & Grobman, W.A. (2018 April 23). Reduction of Peripartum Racial and Ethnic Disparities: A Conceptual Framework and Maternal Safety Consensus Bundle. *Journal of Obstetric, Gynecologic & Neonatal Nursing,* 47(3): 275-89. https://www.jognn.org/article/S0884-2175(18)30064-9/fulltext

[56] Haider, A.H., Schneider, E.B., Sriram, N., Scott, V.K., Swoboda, S.M., Zogg, C.K., Dhiman, N., Haut, E.R., Efron, D.T., Pronovost, P.J., Freischlag, J.A, Lipsett, P.A., Cornwell, E.E., MacKenzie, E.J., & Cooper, L.A. (2015 June). Unconscious Race and Class Biases among Registered Nurses: Vignette-Based Study Using Implicit Association Testing. *Journal of the American College of Surgeons,* 220(6): 1077-86. https://journals.lww.com/journalacs/Abstract/2015/06000/Unconscious_Race_and_Class_Biases_among_Registered.20.aspx

[57] Haider, A.H., Schneider, E.B., Sriram, N., Dossick, D.S., Scott, V.K., Swoboda, S.M., Losonczy, L., Haut, E.R., Efron, D.T., Pronovost, P.J., Freischlag, J.A, Lipsett, P.A., Cornwell, E.E., MacKenzie, E.J., & Cooper, L.A. (2014 September). Unconscious race and class bias: Its association with decision making by trauma and acute care. surgeons. *Journal of Trauma and Acute Care Surgery,* 77(3): 409-16. https://journals.lww.com/jtrauma/Abstract/2014/09000/Unconscious_race_and_class_bias__Its_association.3.aspx

and algorithmic tools used in medical settings can have unintended biases that can exacerbate healthcare challenges for marginalized groups.[58, 59] Community challenges can compound these disadvantages, since people living in under-resourced areas often lack access to medical care[60, 61] and receive care from hospitals that, due to longstanding structural inequities, may not have the necessary staffing or resources to implement best practices for ensuring patient safety.[62] As such, improving patient safety throughout the healthcare system, with a special focus on patients from socially marginalized groups, is critical to advancing health equity.[63, 64]

Recommendation 3: Partner with Patients and Reduce Disparities in Medical Errors and Adverse Outcomes.

It is crucial to engage relevant stakeholders in the nation's effort to reduce harm from unsafe care. This should include partnering and collaborating with the patients, families, and communities most impacted by unsafe care. Implementing evidence-based solutions in healthcare settings should include patient-centered approaches and give special attention to collaborating with those communities that have experienced long-standing disparities. For example, disparities in receiving timely, effective care for hypertensive disorders of pregnancy and post-partum complications such as cardiomyopathy, hemorrhages, and pulmonary emboli, substantially contribute to disparities in maternal morbidity.[65] These symptoms require careful, urgent, and non-biased assessment, which Black patients and people from other marginalized groups are less likely to experience. The issue of healthcare disparities is longstanding and complex, and the recommendations below should not be considered as comprehensive. Rather, they may serve as a complement to other ongoing efforts, including a National Academies committee that conducted an analysis of federal policies that contribute to health disparities[66] and an ad hoc committee of the National Academies of Sciences,

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[58] The White House. (2022 October). Blueprint for an AI Bill of Rights: Making Automated Systems Work for the America People. *Office of Science and Technology Policy.* https://www.whitehouse.gov/wp-content/uploads/2022/10/Blueprint-for-an-AI-Bill-of-Rights.pdf

[59] Krumholz, H.M., & Bernheim, S.M. (2014 December 2). Considering the Role of Socioeconomic Status in Hospital Outcomes Measures. *Annals of Internal Medicine,* 161(11):833-4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5459391/

[60] U.S. House of Representatives. (2020 July). Left Out: Barriers to Health Equity for Rural and Underserved Communities. *Report of the Committee on Ways and Means Majority.* https://sharenm.s3.amazonaws.com/library/U4ReG3RcofVn9Wlae04qsxK8et2upq0UMtvEVZjz.pdf

[61] Lam, O., Broderick, B., & Toor, S. (2018 December 12). How far Americans live from the closest hospital differs by community type. *Pew Research Center.* https://pewrsr.ch/2L2nthb

[62] Viscardi, M.K., French, R., Brom, H., Lake, E., Ulrich, C., & McHugh, M.D. (2022 January 5). Care Quality, Patient Safety, and Nurse Outcomes at Hospitals Serving Economically Disadvantaged Patients: A Case for Investment in Nursing. *Policy, Politics, & Nursing Practice,* 23(1):5-14. https://journals.sagepub.com/doi/10.1177/15271544211069554?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[63] Chin, M.H. (2021 April 19). Advancing health equity in patient safety: a reckoning, challenge and opportunity. *BMJ Quality & Safety,* 30: 356-61. https://qualitysafety.bmj.com/content/30/5/356

[64] Schulson, L.B., Thomas, A.D., Tsuei, J., and Etchegaray, J.M. (2022 August 8). Identifying and Understanding Ways to Address the Impact of Racism on Patient Safety in Health Care Settings. *Santa Monica, CA: RAND Corporation.* https://www.rand.org/pubs/research_reports/RRA1945-1.html

[65] The Joint Commission. (2022 July 27). Diagnostic Overshadowing Worsens Health Disparities. *Blog: Advancing Health Care Equity*. https://www.jointcommission.org/resources/news-and-multimedia/blogs/advancing-health-care-equity/2022/07/diagnostic-overshadowing-worsens-health-disparities/#.ZCbh1hXMK5e

[66] National Academies of Sciences, Engineering, and Medicine (2023). *Federal Policy to Advance Racial, Ethnic, and Tribal Health Equity*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26834

Engineering, and Medicine that is examining the current state of racial and ethnic healthcare disparities in the U.S., including barriers to successful implementation of evidence-based solutions.[67] To partner with patients and reduce and eliminate disparities in patient safety, the President should direct the following activities.

Recommendation 3. A

Implement a "Whole of Society Approach" in the Transformational Effort on Patient Safety.

All relevant federal agencies, committees, and advisory groups should establish policies, structures, budgets, and training for diversifying input on patient safety performance, advancing information at all levels, and implementing evidence-based solutions for tangible progress in advancing healthcare equities for all Americans. Federal agencies should seek meaningful and robust participation of experts in racism and intersectionality; diverse healthcare workers, patients, family members, and patient and community organizations, including people who have experienced harm from unsafe care, patients from communities who experience marginalization; and people who have experienced higher rates of harm such as people with severe mental illness, physical and neurocognitive disabilities, and degenerative conditions such as Parkinson's disease, frontal-temporal dementia, and Alzheimer's disease. Patients, families, and community members should be involved in the development ("co-production") of all phases of patient safety planning, programming, assessment, monitoring and evaluation. There should be a meaningful and transparent process for frontline healthcare workers, patient advocates, family members, and patient and community organizations to participate in all actions related to patient safety. Specifically, community members with lived experiences should be encouraged and or incentivized for sharing their expert advice in this process, such as with financial reimbursements for time and effort. HHS, DoD, DoJ, and VA should establish competitive awards and other incentives for capacity building for patients, family members, and patient or community organizations to enable diverse input into the co-development of patient safety solutions.

Recommendation 3.B

Improve Data and Transparency to Reduce Disparities.

To improve data and transparency to reduce disparities, the President should direct the Secretary of HHS to require AHRQ to lead the development and validation of new questions focused on racial/ethnic bias and patient safety in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, allowing CMS to require collection of patient perceptions of racial/ethnic bias and patient safety through existing surveys. CMS should incentivize healthcare facilities to collect self-reported patient race/ethnicity information as part of their safety improvement efforts. AHRQ should encourage patient safety organizations (PSOs) to collect, analyze, and disseminate information on racial and ethnic disparities in patient safety. The Secretary of HHS should draft a national patient safety rights charter that includes concepts such as patient rights to safety, respect, autonomy, reliable care, information and transparency, and promotes the concept of safe, respectful care as a patient's right.

[67] *Unequal Treatment Revisited: The Current State of Racial and Ethnic Disparities in Healthcare*. Accessed: 2023 August). National Academies of Sciences, Engineering, and Medicine. https://www.nationalacademies.org/our-work/unequal-treatment-revisited-the-current-state-of-racial-and-ethnic-disparities-in-healthcare

Root Causes, Successes, and Ongoing Challenges

Over the past 20 years, patient safety experts have developed effective evidence-based practices such as practices to reduce some hospital acquired infections and increase medication safety, but uniform, nationwide implementation of these strategies is lacking.[68]

Hospitals that have implemented evidence-based solutions, however, have markedly reduced patient harm and death due to medical errors. For example, the implementation of evidence-based solutions in local hospitals, including solutions for central line-associated bloodstream infection (CLABSI)[69] and surgical site infections,[70] have been successful in reducing harm to patients. However, systemic improvements in quality of care–which depend on various factors including institution type and leadership,[71] hospital resources,[72] staffing,[73] training and wellness,[74] and workplace culture[75]–have proven difficult to bring to scale on a volunteer basis, or to sustain.[76] PCAST's recommendations propose solutions for accelerating the adoption of evidence-based solutions, while providing hospital systems and staff with the resources necessary to do so.

One bright spot has been the successes resulting from learning health networks that have convincingly reduced harm rates. Successful examples include CMS's Partnership for Patients, which

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[68] Bates, D. W., & Singh, H. (2018 November). Two Decades Since *To Err Is Human*: An Assessment Of Progress And Emerging Priorities In Patient Safety. *Health Affairs,* 37(11): 1736-1743. https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.0738

[69] Berenholtz, S.M., Lubomski, L.H., Weeks, K., Goeschel, C.A., Marsteller, J.A., Pham, J.C., Sawyer, M.D., Thompson, D.A., Winters, B.D., Cosgrove, S.E., Yang, T., Louis, T.A., Lucas, B.M., George, C.T., Watson, S.R., Albert-Lesher, M.I., St. Andre, J.R., Combes, J.R., Bohr, D., Hines, S.C., Battles, J.B., & Pronovost, P.J. (2014 January). Eliminating Central Line–Associated Bloodstream Infections: A national patient safety imperative. *Infection Control & Hospital Epidemiology,* 35(1): 56-62. https://pubmed.ncbi.nlm.nih.gov/24334799/

[70] Schaffzin, J.K., Harte, L., Marquette, S., Zieker, K., Wooton, S., Walsh, K., & Newland, J.G. (2015 November). Surgical Site Infection Reduction by the Solutions for Patient Safety Hospital Engagement Network. *Pediatrics,* 136(5): e1353-60. https://publications.aap.org/pediatrics/article-abstract/136/5/e1353/33788/Surgical-Site-Infection-Reduction-by-the-Solutions?redirectedFrom=fulltext

[71] Longo, D.R., Hewett, J.E., Ge, B., Schubert, S., & Kiely, R.G. (2007 May/June). Hospital Patient Safety: Characteristics of Best-Performing Hospitals. *Journal of Healthcare Management,* 52(3): 188-204; discussion 204-5. https://www.proquest.com/docview/206738804?pq-origsite=gscholar&fromopenview=true

[72] Encinosa, W.E., & Bernard, D.M. (2005 February). Hospital Finances and Patient Safety Outcomes. *INQUIRY: The Journal of Health Care Organization, Provision, and Financing,* 42(1): 60-72. https://journals.sagepub.com/doi/10.5034/inquiryjrnl_42.1.60?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[73] Shekelle, P.G. (2013 March 5). Nurse-patient ratios as a patient safety strategy: a systematic review. *Annals of Internal Medicine,* 158(5): 404-09. https://www.acpjournals.org/doi/full/10.7326/0003-4819-158-5-201303051-00007?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org

[74] Trockel, M.T., Menon, N.K., Rowe, S.G., Stewart, M.T., Smith, R., Lu, M., Kim, P.K., Quinn, M.A., Lawrence, E., Marchalik, D., Farley, H., Normand, P., Felder, M., Dudley, J.C., & Shanafelt, T.D. (2020 December 7). Assessment of Physician Sleep and Wellness, Burnout, and Clinically Significant Medical Errors. *Journal of the American Medical Association (JAMA) Network Open,* 3(12): e2028111. https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2773777

[75] Weller, J., Boyd, M., & Cumin, D. (2014 January 7). Teams, tribes and patient safety: overcoming barriers to effective teamwork in healthcare. *Postgraduate Medical Journal*, 90(1061):149-54. https://academic.oup.com/pmj/article-abstract/90/1061/149/6992009?redirectedFrom=fulltext

[76] Toor, H., Farr, S., Savla, P., Kashyap, S., Wang, S., Miulli, D.E. (2022 March). Prevalence of Central Line-Associated Bloodstream Infections (CLABSI) in Intensive Care and Medical-Surgical Units. *Cureus.* 2022 Mar 3;14(3):e22809. doi: 0.7759/cureus.22809c. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8976505/

helped to prevent 20,500 hospital deaths between 2014-2017,[77] and regional networks such as Solutions for Patient Safety, a national consortium of children's hospitals who voluntarily share data and ideas to reduce harm.[78] PCAST celebrates these efforts and offers recommendations for expanding their reach and effectiveness. At the same time, PCAST recognizes that the healthcare organizations' executive leadership, Boards, and culture will be critical to the success in any endeavor that seeks to reduce patient harm.

Recommendation 4: Accelerate Research and Deployment of Practices, Technologies, and Exemplar Systems of Safe Care.

Beyond today's knowledge, it is critically important to accelerate the development and deployment of new technologies and evidentiary foundations for safe healthcare, so that errors, injuries and healthcare disparities are minimized. Promising directions include harnessing new practices and technologies for assisting with medication selection and management, as well as diagnosis, monitoring, and predictions about treatment effectiveness based on individual characteristics.

Recommendation 4.A

Develop a National Patient Safety Research Agenda.

HHS through CDC, NIH, and other relevant agencies should develop a ten-year research and development program to harness advances in human factors, safety science, computer science, and health technologies to address health care safety challenges including those linked to healthcare disparities. Safety science, as well as tools and technologies available today in prototype form and in limited deployments hold promise to rapidly increase the ability to predict risk of adverse outcomes, track harms, provide alerts in advance of potential errors, and to, more generally, guide decision making to enhance healthcare quality and reduce unsafe care. Safety enhancing technologies that make use of automated electronic health records as well as data available from devices and sensors touching the patient can enhance patient safety and healthcare quality and reduce the time and effort burden of data collection on health care teams. Special attention should be given to the potential for these advances to exacerbate existing disparities, and appropriate monitoring and safeguards for unintended consequences should be put in place.

Beyond component targeted solutions, more holistic and systems focused studies are needed to understand and address systems-level failures. Leveraging knowledge and experience from the commercial air-transport industry safety efforts, system-level approaches should include empowering hospitals and other elements of the health care system with safety-critical methods, transparency, and a culture of safety. Additionally, studies should focus on improved understanding of disparities, e.g., through stratification of outcomes by demographic and other factors such as geographic-level and hospital characteristics, and reduction of disparities, e.g., through the deployment of interventions focused on mitigating the effects of structural and social barriers and addressing biases in healthcare delivery. Given the challenge of predicting the effects over time of

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[77] Department of Health and Human Services (HHS). (2019 January). AHRQ National Scorecard on Hospital-Acquired Conditions Updated Baseline Rates and Preliminary Results 2014–2017. *Agency for Healthcare Research and Quality (AHQR), Healthcare-Associated Infections Program, National Scorecard Reports.* https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/hacreport-2019.pdf

[78] Lyren, A., Brilli, R.J., Zieker, K., Marino, M., Muething, S., & Sharek P.J. (2017 August 16). Children's Hospitals' Solutions for Patient Safety Collaborative Impact on Hospital-Acquired Harm. *Pediatrics,* 140(3): e20163494. https://publications.aap.org/pediatrics/article-abstract/140/3/e20163494/38408/Children-s-Hospitals-Solutions-for-Patient-Safety?redirectedFrom=fulltext

introducing new programs and interventions to healthcare organizations and to the larger U.S. healthcare system, explicit research and reporting of results should be focused on monitoring the influences of recommended mitigations, with a special focus on progress on mitigating disparities in healthcare delivery.

Recommendation 4.B

Harness Revolutionary Advances in Information Technologies.

Multiple information technologies hold great opportunity for enhancing patient safety, including new forms of event capture from logs, non-invasive sensing and monitoring, data analytics tools, and AI methods for diagnosis, prediction, and generation in healthcare.

As mentioned under recommendation 4.A, advances in information technologies can decrease the data collection burden on front-line healthcare workers while also providing rapid insights into risks of adverse outcomes via visualizations and summaries that can help to guide mitigations.

AI methods for performing diagnosis and prediction from findings in patient data are particularly ripe for being harnessed to boost the accuracy and timeliness of diagnosis and therapy. Applications of AI to date are largely research prototypes with limited deployments. While special care and caution are needed to validate performance on different tasks and effort is needed to integrate AI advances into operational services, including the development of effective designs for human practitioner-AI interaction,[79] much more can be done on research, validation, and in the maturation of applications.[80] AI, particularly the rapid developments in machine learning, when carefully honed, integrated, and leveraged in healthcare environments, hold opportunity to significantly address patient safety challenges in both hospital and outpatient settings. These tools can effectively support clinicians in decision-making, providing advice (e.g., differential diagnoses, ideal testing, information gathering), reminders (e.g., alerts about potentially overlooked evidence-based practices for safety), summaries (e.g., initial drafts of I-PASS reports in support of team transitions), and focusing attention through their capabilities in diagnosis, prediction, treatment planning, and language-based analysis.[81,82,83,84,85]

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[79] Fogliato, R., Chappidi, S., Lungren, M., Fisher, P., Wilson, D., Fitzke, M., Parkinson, M., Horvitz, E., Inkpen, K., & Nushi, B. (2022 June 20). Who Goes First? Influences of Human-AI Workflow on Decision Making in Clinical Imaging. *2022 Association for Computing Machinery (ACM) Conference on Fairness, Accountability, and Transparency,* 1362-74. https://dl.acm.org/doi/abs/10.1145/3531146.3533193

[80] Coalition for Health AI (CHAI). (2023 April 4). Blueprint for Trustworthy AI Implementation Guidance and Assurance for Healthcare. https://www.coalitionforhealthai.org/papers/blueprint-for-trustworthy-ai_V1.0.pdf

[81] Bayati, M., Braverman, M., Gillam, M., Mack, K.M., Ruiz, G., Smith, M.S., & Horvitz, E. (2014 October 8). Data-Driven Decisions for Reducing Readmissions for Heart Failure: General Methodology and Case Study. *PLOS One Medicine,* 9(10): e109264. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0109264

[82] Henry, K.E., Hager, D.N., Pronovost, P.J., & Saria, S.A. (2015 August 15). A targeted real-time early warning score (TREWScore) for septic shock. *Science Translational Medicine*, 7(299): 299ra122. https://www.science.org/doi/abs/10.1126/scitranslmed.aab3719

[83] Wiens, J., Campbell, W.N., Franklin, E.S., Guttag, J., & Horvitz, E. (2014 July 15). Learning Data-Driven Patient Risk Stratification Models for Clostridium difficile. *Open Forum Infectious Diseases Advance Access,* 1(2): ofu045. https://academic.oup.com/ofid/article/1/2/ofu045/1462831

[84] Hauskrecht, M., Batal, I., Valko, M., Visweswaran, S., Cooper, G.F., & Clermont, G. (2013 February). Outlier detection for patient monitoring and alerting. *Journal of Biomedical Informatics,* 46(1): 47-55. https://www.sciencedirect.com/science/article/pii/S1532046412001281

[85] Lee, D.H., Yetisgen, M., Vanderwende, L., & Horvitz, E. (2020 July). Predicting Severe Clinical Events by Learning about Life-Saving Actions and Outcomes using Distant Supervision. *Journal of Biomedical Informatics,* 107: 10425. https://www.sciencedirect.com/science/article/pii/S1532046420300538

Prominent among the emerging technologies are traditional *supervised machine learning* and the more recent *self-supervised technologies*. The latter include recent developments with general-purpose *foundation* models, also referred to as *large language models* (LLMs). These models and their applications in healthcare are nascent yet show early promise for being leveraged in administrative tasks and, with careful testing and validation, with assisting with clinical decision making.[86, 87, 88, 89, 90, 91] While there is opportunity ahead with the harnessing of recent developments with LLMs in healthcare applications, enthusiasm needs to be tempered with careful research and evaluation, and considerations of regulatory oversight with uses.[92]

HHS, through its relevant agencies, including the National Library of Medicine (NLM), AHRQ, CDC, and NIH, in collaboration with the FDA should consider establishing a program of ***AI for Patient Safety*****,** aimed at pooling and sharing best practices, specifying systems, collecting, and making available patient-safety datasets, sharing models and practices, and providing information on integration of technologies for sensing and monitoring, data analytics, and AI systems within current workflows of hospitals. The AI for Patient Safety Program suggested here should work to develop and deploy AI technologies as they are validated, particularly with fast-paced advances in machine learning, on promising directions for patient safety. These efforts should include the list of high-priority harms as an initial focus.

Box 3: Agency collaboration to organize federal healthcare datasets

The NIH, DoD, and VA should coordinate with one another to identify, catalogue, and digitize federal healthcare datasets for use in AI in health care research. For example, the pathology glass slide assets hosted at the Joint Pathology Center can be digitized and made available to unlock new powers of recognition and prediction for enhancing patient safety. That data and other anonymized, privacy-preserving research datasets can be made available to researchers for machine learning studies aimed at creating new technologies to advance excellence in diagnosis, treatment, planning, and disease management across health conditions.

While automated technologies leveraging AI tools hold significant promise when developed using health equity principles and practices, it is critically important to employ best practices, engineering

[86] Singhal, K., Azizi, S., Tu, T., et al. (2023 July). Large language models encode clinical knowledge. *Nature* 620, 172–180 (2023). https://doi.org/10.1038/s41586-023-06291-2
[87] Nori, H., King, N., Mayer McKinney, S., et al. (2023 March). Capabilities of GPT-4 on Medical Challenge Problems, *arXiv*. https://arxiv.org/abs/2303.13375
[88] Lee, P., Bubeck, S., Petro, J. (2023 March). Benefits, limits, and risks of GPT-4 as an AI chatbot for medicine. *New England Journal of Medicine*. https://www.nejm.org/doi/10.1056/NEJMsr2214184
[89] Kanjee, Z., Crowe, B., Rodman, A. (2023 July 3). Accuracy of a Generative Artificial Intelligence Model in a Complex Diagnostic Challenge. *Journal of the American Medical Association (JAMA)*, 2023;330(1):78-80. doi:10.1001/jama.2023.8288. https://jamanetwork.com/journals/jama/fullarticle/2806457
[90] Dash, D., Thapa, R., Banda, J. M., Swaminathan, A., et al. (2023 May 1). Evaluation of GPT-3.5 and GPT-4 for supporting real-world information needs in healthcare delivery. *arXiv*. https://arxiv.org/abs/2304.13714
[91]Strong, E., DiGiammarino, A., Weng, Y., et al. (2023 July 17). Chatbot vs Medical Student Performance on Free-Response Clinical Reasoning Examinations. *JAMA Intern Med.* doi:10.1001/jamainternmed.2023.2909 https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2806980
[92] Meskó, B, & Topol, E. J., (2023 July 6). The imperative for regulatory oversight of large language models (or generative AI) in healthcare. *npj Digital Medicine*, 6:120. https://doi.org/10.1038/s41746-023-00873-0

principles, and monitoring methodologies to detect, characterize, and mitigate challenges with the safety and reliability of the systems and consider fairness, per biases arising in the data and downstream systems constructed from that data for patients of different backgrounds and demographics.[93, 94]

Recommendation 4.C

Develop Federal Healthcare Delivery Systems' Capacities and Showcase Results as Exemplars for Safer Healthcare.

The DoD and VA are well positioned to develop federal health care delivery systems as leading prototypes for safer healthcare. The Secretaries of Defense, HHS, and VA should demonstrate their commitment to patient safety by facilitating implementation of PCASTs recommendations to prioritize dramatic patient safety and workforce safety improvements in their respective healthcare delivery systems, with measurements of systemic progress through regular, public reports to the President. The aim should be bold and clear: Within the next five years, to make the Military Health System, and the Veterans Healthcare System outstanding, instructive examples of safer care for both the nation and internationally. The departments should provide forums to recognize exemplars in patient safety as well as share their best practices with other health systems with particular focus on supporting hospitals serving marginalized populations.

Building on Biden-Harris Administration Efforts

The Biden-Harris administration has taken key steps to improve the quality of healthcare for all Americans. These efforts have focused on tackling cancer,[95] the maternal health crisis,[96] expanding health insurance coverage,[97] lowering healthcare costs,[98] addressing algorithmic discrimination,[99] and advancing health equity.[100] In addition, federal agencies have made important progress in

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[93] Parikh, R.B., Teeple, S., & Navathe, A.S. (2019 November 22) Addressing Bias in Artificial Intelligence in Health Care. *Journal of the American Medical Association (JAMA),* 322(24): 2377-78. https://jamanetwork.com/journals/jama/article-abstract/2756196

[94] Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019 October 25). Dissecting racial bias in an algorithm used to manage the health of populations. *Science,* 366(6464): 447-53. https://www.science.org/doi/10.1126/science.aax2342

[95] The White House. Cancer Moonshot. https://www.whitehouse.gov/cancermoonshot/

[96] The White House. (2022 June 22). White House Blueprint for Addressing the Maternal Health Crisis. https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf

[97] The White House. (2021 January 28). Executive Order on Strengthening Medicaid and the Affordable Care Act. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/28/executive-order-on-strengthening-medicaid-and-the-affordable-care-act/

[98] The White House. (2022 April 5). FACT SHEET: Biden Harris Administration Proposes Rule to Fix "Family Glitch" and Lower Health Care Costs. https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/05/fact-sheet-biden-harris-administration-proposes-rule-to-fix-family-glitch-and-lower-health-care-costs/

[99] The White House. (2022 October). Blueprint for an AI Bill of Rights: Making Automated Systems Work for the America People. *Office of Science and Technology Policy*. https://www.whitehouse.gov/wp-content/uploads/2022/10/Blueprint-for-an-AI-Bill-of-Rights.pdf

[100] The White House. (2021 November 10). FACT SHEET: Biden Administration Announces New Investments to Support COVID-19 Response and Recovery Efforts in the Hardest-Hit and High-Risk Communities and Populations as COVID-19 Health Equity Task Force Submits Final Report. https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/10/fact-sheet-biden-

addressing patient safety through research, education and training, stakeholder engagement, and strengthening standards for healthcare quality. These efforts have been distributed across multiple Departments, including HHS, the Veterans Health Administration (VA), the Department of Defense (DoD), and the Department of Justice. Most recently, HHS launched the National Healthcare System Action Alliance, a learning community comprised of healthcare systems, federal partners, patients and families, and other stakeholders focused on advancing patient safety and healthcare worker safety.[101]

The combination of all of these measures has provided a critical foundation for improving health and healthcare access for all Americans. The Biden-Harris Administration's momentum makes now the right time to renew our focus and commitment to improving patient safety. The next step to ensure benefits are shared by all Americans is to solidify leadership around patient safety at the national level while also ensuring strong roots of support for hospitals and practitioners who are working along all points in the spectrum from the federal to the local level. To that end, PCAST's recommendations suggest actions that can be taken to reduce medical errors and the harms that they cause. We are confident that these recommendations promote long-term strategies to leverage new methods to reduce medical errors along with recent advances in technology, human factors science, data science, and AI to achieve the goal of dramatically, measurably, and sustainably reducing patient harms from errors by 2030.

Even though measuring deaths and other harms linked to healthcare delivery is challenging and our aligned incentives recommendations are bold, audacious action is needed to diminish the large burden on patients and families resulting from medical errors, especially for groups that have been historically marginalized. We appreciate President Biden's keen interest to end suffering for American patients and the opportunity the President has given PCAST to provide recommendations that can dramatically reduce, if not eliminate, patient harm and suffering.

administration-announces-new-investments-to-support-covid-19-response-and-recovery-efforts-in-the-hardest-hit-and-high-risk-communities-and-populations-as-covid-19-health-equity-task/

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Appendix A: External Experts Consulted

PCAST sought input from a diverse group of additional experts and stakeholders. PCAST expresses its gratitude to those listed here who shared their expertise. They did not review drafts of the report, and their willingness to engage with PCAST on specific points does not imply endorsement of the views expressed herein. Responsibility for the opinions, findings, and recommendations in this report and for any errors of fact or interpretation rests solely with PCAST.

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