



# County of Fairfax, Virginia

To protect and enrich the quality of life for the people, neighborhoods and diverse communities of Fairfax County

Date of Award: March 25, 2024

22nd Century Technologies, Inc.  
8251 Greensboro Drive, Suite 900  
McLean, VA 22102

Attention: Yasmin Rafik, Administrator

Reference: RFP2000003489, Continuous Duty Nursing and Temporary Health Care Services

## **Acceptance Agreement**

**Contract Number: 4400012383**

This acceptance agreement signifies a contract award for Continuous Duty Nursing and Temporary Health Care Services. The period of the contract shall be from Date of Award through June 30, 2028 with two (2) one-year renewal options.

The contract award shall be in accordance with:

- 1) This Acceptance Agreement; and
- 2) The terms and conditions of the Memorandum of Negotiation.

Please note that this is not an order to proceed. A Purchase Order constituting your notice to proceed will be issued to your firm. Please provide your Insurance Certificate according to Special Provisions, Section 18.2.o of the RFP within ten (10) business days after receipt of this letter. All questions in regard to this contract shall be directed to the Contract Specialist, Vincenza Githens, at 703-324-6168 or via e-mail at [Vincenza.Githens@fairfaxcounty.gov](mailto:Vincenza.Githens@fairfaxcounty.gov).

Sincerely,

DocuSigned by:

*Lee Ann Pender*

Lee Ann Pender, CPPB  
Director/County Purchasing Agent

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**Department of Procurement & Material Management**  
12000 Government Center Parkway, Suite 427  
Fairfax, VA 22035-0013  
**Website:** [www.fairfaxcounty.gov/procurement](http://www.fairfaxcounty.gov/procurement)  
**Phone** (703) 324-3201, **TTY:** 711, **Fax:** (703) 324-3228

**MEMORANDUM OF NEGOTIATION**  
**Continuous Duty Nursing and Temporary Health Care Services**  
**RFP#2000003489**

The County of Fairfax (hereinafter called the County) and 22nd Century Technologies, Inc. (hereinafter called the Contractor), hereby agree to the following in the execution of Contract 4400012383 (hereinafter called the Contract) for services as proposed in the proposal for the period from Date of Award through June 30, 2028, with two (2) one-year renewals.

The Contract contains the following items:

- a. County's Request for Proposal (RFP) issued May 2, 2023, and all addenda;
- b. Contractor's Technical and Cost Proposals dated May 30, 2023;
- c. Fairfax County Business Associate/Qualified Service Organization Agreement;
- d. This Memorandum of Negotiation; and
- e. Any subsequent amendments to the Contract.

The following provisions were **negotiated** and are included in the Contract:

1. REVISION to Special Provisions Section 4. TASKS TO BE PERFORMED:

The Contractor agrees to begin service provision within 21 calendar days of a request, with the understanding that failure to place the requested position within this timeframe will result in additional agencies being offered the case. Each case will then be awarded to the first agency able to place the requested position.

An inability to place a requested position within 5 working days is a performance issue. A performance improvement plan will be developed by Contractor with approval required by all agencies utilizing the position in question. It is the Contractor's responsibility to address this problem if it arises and propose a solution.

Contractor will provide 4 weeks' notice before a nurse ends an assignment.

2. ADDITION to Special Provisions Section 18. INSURANCE:

18.2.u. Medical Professional liability insurance covering all staff for medical professional services provided pursuant to this Agreement with a per claim limit of not less than the current cap on damages in a medical professional liability claim or suit, as set forth in Virginia Code Section 8.01-581.15.

3. ADDITION to Special Provisions Section 21. REPORTS:

21.1.c. The Contractor agrees to provide documentation of recruitment and placement attempts to the Fairfax County Health Department (FCHD) twice per month as well as on demand within 48 hours using the **FCHD School Health Skilled Nursing Duty Recruitment Log**.

1. The **FCHD School Health Skilled Nursing Duty Recruitment Log** is required for any student who has not been assigned a nurse and does not have skilled nursing coverage Monday through Friday. The Contractor must use the FCHD log. Documentation will be due on the 1<sup>st</sup> and 15<sup>th</sup> of each month. Documentation is required for all newly assigned cases until the case is covered by Contractor. After 2 days of nursing absence, the recruitment log should be initiated to document attempts to find coverage.

Memorandum of Negotiation  
RFP# 2000003489  
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- 21.1.d. For Continuous Duty Nursing Services, Fairfax County Public Schools (FCPS) requires student medications be maintained per FCPS and FCHD policies which include completing a **Medication Authorization for Students with Skilled Nursing Service Release and Indemnification Agreement** form for each student served who requires medication on FCPS premises. Contractor will complete this form for each applicable student served.

4. ADDITION to Special Provisions Section 22. PAYMENTS:

- 22.5. The Contractor agrees to pay 50% of all costs associated with training a new hire for Temporary Health Care Services if the new hire stays less than 30 days.
- 22.6. Overtime hours for Temporary Health Care Services must be pre-approved by each using county agency. Agency nurse shifts may be extended to avoid gaps in student or client services up to 4 hours without pre-approval.
- 22.7. The County agrees to pay time and one half for Temporary Health Care Services provided on Fairfax County Government-designated holidays if holiday pay is also offered to employees/contractors assigned under this contract by the Contractor.
- 22.8. The County will pay nurses' salaries during security clearance processes and facility trainings.

5. ADDITION to Special Provisions Section 33. AMERICANS WITH DISABILITIES ACT REQUIREMENTS:

- 33.3. The Contractor must notify the County in writing of all religious or Americans with Disabilities Act (ADA) accommodations provided to allow the County to review and determine support needed. The Contractor is responsible for maintaining documentation in adherence with federal requirements for employees and contractors who require ADA accommodations.

6. REVISION to Appendix B, Continuous Duty Nursing Services Tasks to be Performed:

- a. Make individual nursing services available to medically involved school aged children, ages 2 to 21, based on the needs of that student within 21 calendar days of receiving the referral. These one-on-one skilled nursing services shall be provided by an RN or LPN. The Contractor agrees to begin service provision within 21 calendar days of a request, with the understanding that failure to place the requested position within this timeframe will result in additional agencies being offered the case. Each case will then be awarded to the first agency able to place the requested position.
- h. Provide backup nursing coverage which is able to meet the needs of the student within three (3) school days. Vendor will provide nursing needed for start of school within 21 calendar days of request.

7. ADDITION to Appendix B, Continuous Duty Nursing Services Task to be Performed:

- l. An inability to place a requested position within 5 working days is a performance issue. A performance improvement plan will be developed by Contractor with approval required by all agencies utilizing the position in question. It is the Contractor's responsibility to address this problem if it arises and propose a solution.
- m. Contractor will provide 4 weeks' notice before a nurse ends an assignment.

## Memorandum of Negotiation

RFP# 2000003489

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8. Contractor accepts the following rates of compensation:

	HOURLY DIRECT RATE	HOURLY OVERHEAD RATE	TOTAL (BILL RATE TO FAIRFAX COUNTY)
Continuous Duty Nursing RN	-	-	\$65.60
Continuous Duty Nursing LPN	\$40.45	\$17.33	\$57.78
Temporary Health Care RN	\$41.55	\$5.67	\$47.22
Temporary Health Care LPN	\$31.77	\$4.25	\$36.02
Temporary Health Care CNA	\$19.49	\$3.02	\$22.51
Temporary Health Care X-Ray Technician	\$28.32	\$12.14	\$40.45
Temporary Health Care Pharmacist	-	-	\$69.00
Temporary Health Care Pharmacy Technician	-	-	\$25.00
Temporary Health Care Behavioral Health Nurse/Case Manager	\$60.67	\$26.00	\$86.67
Temporary Health Care Behavioral Health Specialist I	\$34.38	\$14.73	\$49.11
Temporary Health Care Behavioral Health Specialist II	\$44.49	\$19.07	\$63.56
Temporary Health Care Administrative Assistant	\$23.25	\$9.97	\$33.22
Temporary Health Care Developmental Disability Specialist I	\$25.28	\$10.83	\$36.11
Temporary Health Care Developmental Disability Specialist II	\$35.39	\$15.17	\$50.56
Temporary Health Care Case Aide	\$20.48	\$8.78	\$29.25
Temporary Health Care Case Worker	\$45.50	\$19.50	\$65.00

ACCEPTED BY:

DocuSigned by:

Isha Sharma

F8A2F337FB424AE...

Signature

Contracts Manager

Title

DocuSigned by:

Lee Ann Pender

E239B762E609465...

Lee Ann Pender, Director/County Purchasing Agent  
Department of Procurement and Material Management

3/19/2024

Date

3/25/2024

Date

Fairfax County Health Department School Health Skilled Nursing Duty Recruitment Log

STUDENT NAME	DOB				
SCHOOL NAME	SCHOOL YEAR	GRADE			
NURSING AGENCY NAME	COMPLETED BY				
DAYS CONTINOUS DUTY NURSING REQUESTED	MON	TUES	WED	THURS	FRI
DAYS UNCOVERED	MON	TUES	WED	THURS	FRI
REASON UNCOVERED					

DATE			
CANDIDATES INTERVIEWED	YES		NO
RECRUITMENT AD POSTED	YES		NO
NOTES			

DATE			
CANDIDATES INTERVIEWED	YES		NO
RECRUITMENT AD POSTED	YES		NO
NOTES			

DATE			
CANDIDATES INTERVIEWED	YES		NO
RECRUITMENT AD POSTED	YES		NO
NOTES			

<b>DATE</b>			
<b>CANDIDATES INTERVIEWED</b>	<b>YES</b>		<b>NO</b>
<b>RECRUITMENT AD POSTED</b>	<b>YES</b>		<b>NO</b>
<b>NOTES</b>			



## MEDICATION AUTHORIZATION FOR STUDENTS WITH SKILLED NURSING SERVICE Release and Indemnification Agreement

**PLEASE READ INFORMATION AND PROCEDURES ON REVERSE SIDE**

<b>PART I PARENT OR GUARDIAN TO COMPLETE</b>				
<p>I hereby authorize Fairfax County Public Schools (FCPS), Fairfax County Health Department (FCHD), and authorized skilled nursing vendor personnel to administer medication as directed by this authorization. I agree to release, indemnify, and hold harmless FCPS, FCHD, and authorized nursing vendor, and any of their officers, staff members, or agents from lawsuits, claims, expenses, demands, or actions, etc., against them for helping this student use medication, provided FCPS, FCHD, and authorized nursing vendor staff members comply with the licensed prescriber, parent or guardian orders set forth in accordance with the provision of Part II below. <b>I have read the procedures outlined on the back of this form and assume responsibility, as required.</b></p>				
<p>Has the student taken the <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, the first full dose must be given at home to ensure that the student does not have a negative reaction.)          listed medications before? First dose was given: Date: _____ Time: _____</p>				
Student Name: Last		First		Middle
Date of Birth	School Name			School Year
<p>No School Board employee or contracted nursing vendor shall administer medication or treatment, as an exception under School Board policy, unless the principal or his or her designee has personally reviewed all the required clearances. I give permission to contact the below named licensed prescriber to clarify information provided on the order should the need arise.</p>				
Parent or Guardian Signature _____		Daytime Telephone _____		Date _____
<b>PART II PARENT OR GUARDIAN TO COMPLETE LIST OF MEDICATIONS STUDENT RECIEVES DURING SCHOOL DAY BY SKILLED NURSE PROVIDER AND SIGN FOR OVER-THE-COUNTER MEDICATION PER MANUFACTURER'S RECOMMENDATION FOR RELIEF OF SYMPTOMS FOR HEADACHE, MUSCLE ACHE, ORTHODONTIC PAIN, OR MENSTRUAL CRAMPS AND FOR ANTIBIOTIC AND ANTIVIRAL MEDICATION FOR UP TO TEN CONSECUTIVE SCHOOL DAYS. LICENSED PRESCRIBER MUST COMPLETE AND SIGN FOR ALL OTHER MEDICATIONS.</b>				
<p>The Fairfax County Health Department and Fairfax County Public Schools discourage the use of medication by students in school during the school day. Any necessary medication that possibly can be taken before or after school should be so prescribed.</p>				
Medication Name	Dose	Diagnosis	Route (Oral, Injection, Inhalation, Topical, Buccal, Rectal, etc)	
Effective Date: _____		<div style="display: flex; justify-content: space-between;"> <span>Current School Year <b>OR</b> From _____ To _____</span> </div>		
Licensed Prescriber Name (Print or Type Below)		<div style="display: flex; justify-content: space-between;"> <span>_____</span> <span>_____</span> <span>_____</span> </div>		
		<div style="display: flex; justify-content: space-between;"> <span>Licensed Prescriber Signature</span> <span>Telephone or Fax</span> <span>Date</span> </div>		
Parent or Guardian Name (Print or Type Below) (Not required if licensed prescriber signs)				

	Parent or Guardian Signature	Telephone	Date
<b>PART III PRINCIPAL OR PRINCIPAL DESIGNEE TO COMPLETE</b>			
Check <input checked="" type="checkbox"/> as appropriate:			
<input type="checkbox"/> Parts I & II above are complete including signatures. (It is acceptable if all items in Part II are written on the licensed prescriber's stationery or a prescription pad.) <input type="checkbox"/> Medication is appropriately labeled in original containers . _____			
Principal or Principal Designee Signature _____		Date _____	

Information from the Fairfax County Public Schools student scholastic record is released on the condition that the recipient agrees not to permit any other party to have access to such information without the written consent of the parent, guardian, or eligible student.

## PARENT/GUARDIAN INFORMATION ABOUT MEDICATION PROCEDURES

1. Medications should be taken at home whenever possible so that the student will not lose valuable classroom time or have a shortened lunch period. Any medication taken in school must have a parent or guardian-signed authorization; some medications also require licensed prescriber's orders. Medication must be kept in the school-approved location during the school day. **The skilled nursing provider must transport medications to and from school in locked storage device.**
2. No medication will be accepted by school or nursing agency personnel without receipt of completed and appropriate medication forms. Only a 30-day supply of medication should be brought into school at a time.
3. A licensed prescriber may use office stationery or a prescription pad in lieu of completing Part II. Include the following information written in lay language with no abbreviations:
  - Name of student
  - Date of birth
  - Reason for medication or diagnosis
  - Name of medication
  - Exact dosage to be taken in school (e.g., mg, ml, or cc)
  - Route of administration
  - Time to take medication and frequency or exact time interval dosage is to be administered
  - Sequence in which the medications should be taken in cases where more than one medication is prescribed
  - If medication is given on an as-needed basis, specify the exact conditions or symptoms when medication is to be taken and the time at which it may be given again. ("Repeat as necessary" is unacceptable.)
  - Duration or effective dates of medication order
  - Licensed prescriber's signature and date
4. All prescription medications, including licensed prescriber's prescription drug samples, **must** be in their original containers and labeled by a licensed prescriber or pharmacist. An over-the-counter medication **must** be in the original container with the name of the medication visible. For over-the-counter medications, the parent or guardian must label the original container with the following:
  - Name of student
  - Route of administration
  - Exact dosage to be taken in school (e.g., mg, ml, or cc)
  - Frequency or time interval dosage is to be administered
5. **The first dose of any new medication must be given at home.**
6. The parent or guardian is responsible for submitting a new form to the school at the start of the school year and each time there is a change in the dosage or in the time at which medication is to be taken.
7. Medication kept in the school will be stored in a locked area accessible only to authorized personnel.
8. Within one week after expiration of this authorization or on the last day of school, the parent or guardian must pick up any unused portion of the medication. Medications not claimed within that period will be destroyed.
9. The Fairfax County Health Department, Fairfax County Public Schools, and the authorized skilled nursing vendor do not assume responsibility for authorized medication taken independently by the student.
10. In no case may any health, school, or authorized nursing agency staff member administer any medication outside the framework of the procedures outlined here and/or in FCPS regulations.

11. The parent or guardian must provide the authorized nursing agency staff member with a supply of medication to be administered during the school day.
12. The parent is responsible for immediately notifying the nursing agency of changes to medication.

SAMPLE

**FAIRFAX COUNTY  
BUSINESS ASSOCIATE/ QUALIFIED SERVICE ORGANIZATION AGREEMENT**

This Business Associate/Qualified Service Organization Agreement ("Agreement") is entered into this 25th day of March 2024, by and between Fairfax County ("Covered Entity" or "County"), and 22nd Century Technologies, Inc. ("Business Associate"), as defined in Section 1.1 below.

**RECITALS**

A. Fairfax County is a Hybrid Covered Entity. The County's covered components, including the Fire and Rescue Department, Health Department, Sheriff's Office Medical Branch, and the Fairfax-Falls Church Community Services Board ("CSB"), are subject to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The CSB and the Juvenile and Domestic Relations District Court's Alcohol Safety Action Program ("ASAP") are also "Part 2 programs," as defined by and the Confidentiality of Substance Use Disorder Patient Records, 42 C.F.R. Part 2, Subpart A through Subpart E, ("42 CFR Part 2").

B. Business Associate is 22nd Century Technologies, Inc.

C. The parties desire to enter into this Agreement regarding the use and/or disclosure of Protected Health Information ("PHI") as required by HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (Division A, Title XIII and Division B, Title IV, of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) (the "HITECH Act"), and their implementing regulations, including the Federal Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subparts A and E (the "Privacy Rule"), the Security Standards for the Protection of Electronic Protected Health Information, 45 C.F.R. Part 160 and Part 164, Subpart C (the "Security Rule"), and 42 CFR Part 2.

NOW, THEREFORE, in consideration of the mutual promises set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

**1. DEFINED TERMS.**

1.1. Defined Terms. Capitalized terms used, but not otherwise defined in this Agreement, have the same meaning given to such terms in HIPAA, the HITECH Act, or the implementing regulations promulgated there under, including but not limited to the Privacy and Security Rules at 45 C.F.R. Part 160 and 45 C.F.R. Part 164. For purposes of this Agreement,

(a) "Covered Entity" means Fairfax County, and any Affiliate, and shall generally have the same meaning as the term "covered entity" at 45 C.F.R. § 160.103 and the term "Part 2 program" defined in 42 C.F.R. § 2.11;

(b) “Business Associate” means 22nd Century Technologies, Inc. in reference to this Agreement, and shall have the same meaning as the term “business associate” at 45 C.F.R. § 160.103, and the term “qualified service organization” as defined in 42 C.F.R. § 2.11;

(c) “Affiliate” means any entity that Controls, is under the Control of, or is under common Control with, the Covered Entity; “Affiliate” also means any entity that Controls, is under the Control of, or is under common Control with the Business Associate;

(d) “Control” or “Controls” means possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity;

(e) “Protected Health Information” or “PHI” means individually identifiable health information, and includes Patient Identifying Information relating to Clients of the CSB and ASAP as defined by 42 C.F.R. § 2.11;

(f) “Client” refers to patients and other individuals who receive and have received services from Fairfax County, and for whom the County maintains any PHI.

## **2. BUSINESS ASSOCIATE OBLIGATIONS.**

2.1. Business Associate Status. Business Associate acknowledges and agrees that it is a “business associate” as defined by the Privacy and Security Rules.

2.2. Business Associate’s Use or Disclosure of PHI. Business Associate may use or disclose PHI only as necessary to perform the services set forth in the parties’ Contract 4400012383, and only to the extent such use or disclosure of PHI (a) would not violate the Privacy Rule if done by the County, (b) is reasonably limited to the minimum necessary information to accomplish the intended purposes of the use or disclosure; (c) is in compliance with each applicable requirement of 45 C.F.R. § 164.504(e); (d) is in compliance with the HITECH Act and its implementing regulations; and (e) is in compliance with 42 CFR Part 2. Business Associate shall not use or disclose PHI other than as permitted or required by this Agreement or by applicable law.

2.3. Safeguards for Protection of PHI.

(a) Business Associate will use appropriate safeguards to prevent use and/or disclosure of PHI other than as provided for by this Agreement.

(b) Business Associate will comply with applicable Security Rule provisions set forth at 45 C.F.R. Part 164, Subpart C, including provisions relating to Security Standards General Rules (45 C.F.R. §164.306), Administrative Safeguards (45 C.F.R. § 164.308), Physical Safeguards (45 C.F.R. § 164.310), Technical Safeguards (45 C.F.R. § 164.312), Organizational Requirements (45 C.F.R. §164.314) and Policies and Documentation (45 C.F.R. § 164.316), and implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic PHI that Business Associate creates, receives, maintains or transmits on behalf of the County.

(c) To the extent Business Associate is to carry out an obligation of the County under the Privacy Rule provisions set forth at 45 C.F.R. Part 164, Subpart E as directed by the County pursuant to the terms of this Agreement, Business Associate will comply with the requirements of the Privacy Rule that apply to the County in the performance of such obligation.

(d) To the extent Business Associate includes information received from the County in research reports, such information may only be published in aggregate form in which PHI has been rendered non-identifiable such that the information cannot be re-identified.

(e) To the extent Business Associate receives, stores, processes, or otherwise deals with substance use disorder patient records, it is fully bound by 42 CFR Part 2, including the requirement to resist any efforts to obtain access to PHI related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by 42 CFR Part 2. PHI protected by 42 CFR Part 2 may be disclosed only back to the County and may only be used as authorized by this Agreement or 42 CFR Part 2.

(f) Business Associate will retain records in compliance with applicable record retention laws and will comply with applicable record security provisions of 42 C.F.R. § 2.16 for the maintenance and destruction of PHI contained in substance use disorder patient records.

#### 2.4. Notification.

(a) Business Associate will promptly report to Fairfax County's HIPAA Compliance Officer any use or disclosure of PHI not provided for by this Agreement of which Business Associate becomes aware. This includes, but is not limited to, reporting breaches of Unsecured Protected Health Information as required at 45 C.F.R. 164.410.

(b) Business Associate will report to Fairfax County's HIPAA Compliance Officer any Security Incident of which it becomes aware, in the following time and manner:

i. any actual, successful Security Incident will be reported in writing within three (3) business days of the Business Associate's discovery of such actual, successful Security Incident.

ii. For any actual, successful Security Incident, or for any attempted, unsuccessful, Security Incident of which Business Associate becomes aware, Business Associate shall promptly complete a breach assessment tool (Appendix A) and provide the completed assessment to Fairfax County's HIPAA Compliance Officer within three (3) business days of completion.

(c) Subject to any law enforcement delay required under 45 C.F.R. § 164.412, Business Associate will report to Fairfax County's HIPAA Compliance Officer in writing any Breach of Unsecured PHI within three (3) business days of discovery, and any such report shall include the identification of each individual whose Unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, used or disclosed as a result of any such potential Breach, together with such other information regarding the potential Breach as is known to Business Associate at the time such report is made (such as the type of PHI involved in the event, the nature of the information accessed, acquired or disclosed, etc.) or promptly thereafter as such other information becomes available.

i. The County may require Business Associate to provide Notice to Individuals affected by a Breach caused by Business Associate, as required by 45 C.F.R. § 164.404. If the County provides the required Notice to Individuals as a result of Business Associate's Breach, the County reserves the right to be reimbursed by Business Associate all direct and indirect costs related to providing such Notice.

2.5. Mitigation. Business Associate will mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement or as the result of any Security Incident known to Business Associate.

2.6. Cooperation. Business Associate will work cooperatively with the County in connection with the County's investigation of any Breach and in connection with any notices the County determines are required as a result.

2.7. Subcontractors. Business Associate will ensure that any subcontractor that creates, receives, maintains or transmits PHI on behalf of Business Associate agrees to the same restrictions and conditions that apply through the applicable Engagement and this Agreement to Business Associate with respect to such PHI.

2.8. Client Rights Regarding PHI. The Privacy Rule grants Clients certain rights with regard to the PHI maintained in a "Designated Record Set" (as such term is defined in 45 C.F.R. § 164.501) about them. The County hereby agrees that the PHI provided to Business Associate shall not constitute a Designated Record Set or shall be limited to duplicates of information maintained in a Designated Record Set by the County. However, to the extent Business Associate maintains PHI for an Individual in a Designated Record Set, Business Associate shall provide access to such PHI to the County or, as directed by the County, to an Individual in order to meet the requirements under 45 C.F.R. § 164.524. Business Associate shall document disclosures of PHI and such information related to such disclosures as would be required for the County to respond to a request by a Client for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528 (and HITECH Act § 13405(c) when such requirements are effective as to the County), and shall provide such information to the County promptly upon written request by the County. Business Associate shall notify the County promptly if Business Associate receives a request from a Client to access, amend or receive an accounting of disclosures of Client's PHI.

2.9. Books and Records.

(a) If Business Associate receives a request from the Secretary of Health and Human Services (the "Secretary") that Business Associate make available its internal practices, books and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, the County, to the Secretary for purposes of determining The County's compliance with the Privacy Rule, Business Associate shall promptly notify the County that it has received such a request. Upon Business Associate's receipt of a written directive to do so from the County, Business Associate will make the relevant internal practices, books, and records relating to the use and disclosure of PHI available to the Secretary.

(b) Nothing in this section shall be construed to require Business Associate to disclose or produce to the Secretary communications that are subject to attorney-client privilege held by Business Associate with respect to legal advice it seeks from other legal counsel. Although Business Associate and the County are making a good faith effort to achieve conformance of these terms and conditions with the requirements of applicable law, the County acknowledges that Business Associate has not represented or warranted to the County, that these terms and conditions,

including the procedures outlined in this paragraph, will be deemed by the Secretary or a court to satisfy the requirements of the Privacy and Security Rules or the HITECH Act.

(c) Fairfax County's HIPAA Compliance Officer may make a written request that Business Associate make available its internal HIPAA documents and records, whether in hardcopy or electronic form, to the County for purposes of determining Business Associate's compliance with HIPAA. For purposes of this BAA, "internal HIPAA documents and records" means HIPAA policies and procedures, risk assessments, training records, electronic systems, and other practices, books, and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Fairfax County. Upon Business Associate's receipt of the written request, Business Associate will make the relevant internal records available to Fairfax County's HIPAA Compliance Officer.

**2.10. Use or Disclosure for Business Associate Administration.**

Except as otherwise limited by the terms of this Agreement:

(a) Business Associate may use PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate; and

(b) Business Associate may disclose PHI for the proper management and administration of Business Associate, provided that disclosures are Required by Law or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

**2.11. Reporting of Violations of Law.** Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with the Privacy Rule.

**3. OBLIGATIONS OF COVERED ENTITY.**

**3.1. Notice of Privacy Practices.** As applicable, the County shall notify Business Associate in writing of any and all limitations in its notice of privacy practices or its policies or procedures to the extent that any such limitation may affect Business Associate's use or disclosure of PHI.

**3.2. Notice of Modifications.** The County shall notify Business Associate in writing of any changes in, or revocation of, an authorization or other permission

by a Client to use or disclose PHI to the extent that such change or revocation may affect the use or disclosure of PHI by Business Associate or its subcontractors.

3.3. Special Restrictions. The County shall notify Business Associate in writing of any restriction to the use or disclosure of PHI that the County has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

3.4. Scope of Requests for Use or Disclosure. Except for the uses and disclosures of PHI contemplated by Sections 2.2 and 2.10 above, the County shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under HIPAA, the HITECH Act, their implementing regulations, or 42 CFR Part 2, if done by the County.

#### **4. TERM AND TERMINATION.**

4.1. Term. This Agreement shall be effective on the date first written above, and shall expire upon termination of the parties' underlying Contract.

4.2. Termination by Covered Entity. Upon the County becoming aware of a breach of this Agreement by Business Associate, the County shall provide written notice of and an opportunity for Business Associate to cure the breach or end the violation of the Agreement. If the breach is not cured or the violation is not terminated within forty-five (45) days of the date of such notice the County may terminate this Agreement. Multiple breaches of this Agreement or violations by the Business Associate may result in termination of this Agreement with thirty (30) days' notice to Business Associate and without an opportunity to cure any further breach or violation.

4.3. Return of PHI. Upon any termination, expiration or non-renewal of this Agreement, Business Associate will return or, at the request and expense of the County, destroy any PHI that Business Associate, its agents, or subcontractors then maintains in any form. If, however, Business Associate or the County determine that such return or destruction is not feasible, such PHI will not be returned or destroyed and Business Associate will remain bound by the provisions of this Agreement as to such retained PHI until such PHI is returned to the County or destroyed.

#### **5. MISCELLANEOUS**

5.1. Notices. Any notice required or permitted under this Agreement will be given in writing to –

the Covered Entity at:

Tanya Bullock, HIPAA Compliance Officer  
12000 Government Center Parkway, Suite 553  
Fairfax, VA 22035  
Phone: (703) 324-2164  
hipaacomplianceofficer@fairfaxcounty.gov

the Business Associate at:

Name, Title: Isha Sharma - Contracts Manager  
Address: 8251 Greensboro Drive  
City, State, Zip: Mclean, VA 22102-3827  
Phone: 888-998-7284  
Email: response@tscti.com

Notices will be deemed to have been received upon actual receipt, one business day after being sent by overnight courier service, or five (5) business days after mailing by certified or priority mail, whichever occurs first.

5.2. Governing Law. This Agreement will be governed by, and construed in accordance with, the laws of the Commonwealth of Virginia, without regard to its conflicts of laws principles.

5.3. No Third-Party Beneficiaries. This Agreement shall not in any manner whatsoever confer any rights upon or increase the rights of any third party.

5.4. Waiver. No delay or omission by either party to exercise any right or remedy under this Agreement will be construed to be either acquiescence or the waiver of the ability to exercise any right or remedy in the future.

5.5. Severability. In the event any part or parts of this Agreement are held to be unenforceable, the remainder of this Agreement will continue in effect.

5.6. Amendments. This Agreement may not be modified in any respect other than by a written instrument signed by both parties.

5.7. Assignment. This Agreement is not assignable by either party without the other party's written consent.

5.8. Renegotiation. The parties agree to negotiate in good faith any modification to this Agreement that may be necessary or required to ensure consistency with amendments to and changes in applicable federal and state laws and regulations, including but not limited to, HIPAA, the Privacy and Security Rules, the HITECH Act, regulations promulgated pursuant to HIPAA or the HITECH Act, and 42 CFR Part 2.

5.9. Regulatory and Statutory References. Any reference in this Agreement to HIPAA, the HITECH Act, the Privacy Rule the Security Rule, other regulations implementing HIPAA or the HITECH Act, or 42 CFR Part 2 shall mean such statute or regulation as in effect at the time of execution of this Agreement or, if and to the extent applicable, as subsequently updated, amended or revised.

5.10. Interpretation. Any ambiguity in the Agreement shall be resolved in favor of a meaning that permits the parties to comply with HIPAA and 42 CFR Part 2.

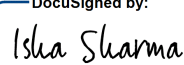
5.11. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

5.12. Scope and Effect of Agreement. This Agreement sets forth the entire agreement and understanding between the parties relating to the subject matter hereof and supersedes and replaces, from the date of this agreement, all other prior discussions, representations, agreements and understandings of every kind or nature, whether oral or written, with respect to the subject matter here of, including without limitation each previously existing business associate agreement, if any, between Business Associate and the Covered Entity.

5.13. Survival. The provisions of Section 4.3 and Section 5 shall survive the termination of this Agreement.

IN WITNESS THEREOF, the parties have executed this Agreement as of the dates written below.

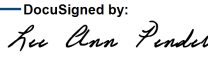
**22nd Century Technologies, Inc.**  
(Business Associate)

By:   
F8A2F337FB124AE...

Name and Title: Isha Sharma  
Contracts Manager

Date: 2/8/2024

**Fairfax County**  
(Covered Entity)

By:   
E239B762E000465...

Name and Title:  
Lee Ann Pender Director

Date:  
3/25/2024



# HIPAA Compliance Program

## Breach Notification Risk Assessment Tool

### Summary of HIPAA Breach Notification Rule, 45 CFR § 164.400-414

The Fairfax County HIPAA Compliance Program and the HIPAA Breach Notification Rule requires HIPAA covered entities[functions] and their business associates to provide notification following a breach of unsecured protected health information (PHI). A breach is, generally, an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of protected health information. An impermissible use or disclosure is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates through a thorough risk assessment (as outlined below) that there is a low probability that the PHI has been *compromised* based on a risk assessment of at least the following factors:

1. The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;
2. The unauthorized person who used or had access to the protected health information or to whom the disclosure was made;
3. Whether the protected health information was actually acquired or viewed; and
4. The extent to which the risk to the protected health information has been mitigated.

**Was Protected Health Information (PHI) Involved?** PHI is health information that identifies, or there is a reasonable basis to believe it can be used to identify, the individual. Health information includes any demographic information of the individual (e.g. name, address, birth date, Social Security number, medical record number) and information relating to the physical or mental health or condition of an individual, the health care provided to an individual (e.g. diagnosis, treatment plan, medication, medical history and test results), or payment for health care provided to an individual:

☐ Yes ☐ No

If yes, PHI was involved, please continue completing this risk assessment tool.

If no, PHI was not involved, then no breach occurred.

**Date Incident  
Occurred:**

**Date Incident Reported:**

**Breach Notification Due Date:**

*(If applicable, 60 days from incident report date)*



# HIPAA Compliance Program

## Breach Notification Risk Assessment Tool

**Name & Title of Person Who Reported Incident:**

**Brief Description of Incident**

1. Who accessed or disclosed the PHI?
2. Was the person authorized to access the PHI? Explain why or why not.
3. How did the person access and/or disclose the PHI? Explain in detail.
4. What was the person's explanation for accessing and/or disclosing the PHI?
5. Was the PHI received by the intended recipient?
6. What did the intended recipient do with the PHI? Was the PHI forwarded to any other person or entity?
7. Was the PHI recovered and/or did the HIPAA Privacy & Security Officers receive confirmation that the PHI was destroyed?
8. Was the incident reported to law enforcement? If so, include name of agency, name of contact at agency (if known), date reported, report number and known status.

**Description of PHI (*e.g., Type of Information, Fields, # of Records*):**



# HIPAA Compliance Program

## Breach Notification Risk Assessment Tool

**Was PHI accessed, used, or disclosed as permitted by the Privacy Rule?** (Was use or disclosure limited to the “minimum necessary” for treatment, payment and health care operations (TPO)?)

☐ Yes ☐ No

If yes, PHI was accessed, used or disclosed as permitted by the Privacy Rule, then no breach occurred and you may conclude this assessment. Reporting is not required under HIPAA.

If no, PHI accessed, used or disclosed was not limited to the “minimum necessary” for TPO, please continue to the next question.

**Was information held by <insert name of organization> in its capacity as an employer?** (For example, <name of organization> obtains PHI from another entity and uses/discloses PHI information for purposes of FMLA, Workers Compensation, and/or HR employment related activities. If <name of organization> obtains and uses PHI in this capacity, then it is not considered PHI and not considered a breach.)

☐ Yes ☐ No

If yes, then no breach occurred and you may conclude this assessment. Reporting is not required under HIPAA.

If no, then please continue to the next question.

**Was PHI encrypted, destroyed or properly de-identified (limited data set with no direct identifiers *and* does not include dates of birth or zip codes)?**

☐ Yes ☐ No

If yes, then no breach occurred and you may conclude this assessment. Reporting is not required under HIPAA.

If no, then please continue to the next question.



# HIPAA Compliance Program

## Breach Notification Risk Assessment Tool

**Does an exception to the Breach Notification Rule apply? Please review Exceptions A-C below.**

☐ Yes ☐ No

If yes, Exception A, B or C applies (please check one below), then no breach occurred and you may conclude this assessment. Reporting is not required under HIPAA.

If no, Exception A, B or C does not apply, then please continue to the Risk Assessment below.

☐ **Exception A.** Was PHI unintentionally accessed or used by a workforce member (employee, volunteer, trainee) or person acting under the authority of a covered entity or business associate within his/her scope of authority, and the PHI was not further impermissibly used/disclosed?

☐ Yes ☐ No

Briefly explain your answer: \_\_\_\_\_

☐ **Exception B.** Was PHI inadvertently disclosed by an authorized person at a covered entity or business associate to another authorized person at the same covered entity or business associate, and the PHI was not further impermissibly used/disclosed?

☐ Yes ☐ No

Briefly explain your answer: \_\_\_\_\_

☐ **Exception C.** Does covered entity or business associate have a good faith belief that the unauthorized person to whom the disclosure was made would not reasonably have been able to retain the information? (For example, PHI sent via mail to the wrong address and returned unopened could not reasonably have been read or retained by the improper addressees.)

☐ Yes ☐ No

Briefly explain your answer: \_\_\_\_\_

### Risk Assessment

An acquisition, access, use or disclosure of PHI in a manner not permitted by the Privacy Rule is presumed to be a breach and must be reported unless the covered entity demonstrates that there is a low probability that the PHI has been compromised based on a risk assessment of at least the factors listed below.

Can this breach be determined to have a **low probability** that the PHI was compromised based on the following assessment?



# HIPAA Compliance Program

## Breach Notification Risk Assessment Tool

**1) What type and amount of PHI was involved and how likely is it that individuals could be identified if PHI is combined with other available information?** Consider whether more sensitive identifiable information was involved (e.g., date of birth, SSN, financial information) or sensitive clinical information (e.g. mental health, test results, STD results) that could increase the risk of identity theft, financial fraud, reputational or other harm to the individual.

☐ Yes, this factor supports low probability of compromise. ☐ No

Describe the nature and amount of the PHI:

**2) Who impermissibly used the PHI and/or to whom was the PHI impermissibly disclosed?** Consider this factor if the PHI was impermissibly used or disclosed within or outside of the County. Consider whether the person has legal obligations to protect the information. For example, is the person a covered entity required to comply with HIPAA, or a government employee, etc.? If so, there may be a lower probability that the PHI has been compromised.

☐ Yes, this factor supports low probability of compromise. ☐ No

Describe who received or used the PHI:

**3) Was the PHI actually acquired or viewed or was there only the opportunity to acquire or view but actual viewing or acquisition of PHI did not occur?** (If electronic PHI is involved, this may require a forensic analysis of the computer to determine whether the PHI was accessed, viewed, acquired, transferred or otherwise compromised.)

☐ Yes, this factor supports low probability of compromise. ☐ No

Describe whether the PHI was actually acquired or viewed:

**4) To what extent was the risk to the PHI mitigated?** For example, by obtaining the recipient's satisfactory assurances that the PHI will not be further used or disclosed (through a confidentiality agreement, declaration or similar means), has been returned, or has been/will be destroyed.

☐ Yes, this factor supports low probability of compromise. ☐ No

Describe steps <name of organization> took or intends to take to mitigate risk:



# HIPAA Compliance Program

## Breach Notification Risk Assessment Tool

### **Breach Risk Assessment Result**

<Name of organization> performed a breach risk assessment, as required under the Department of Health and Human Services, Breach Notification for Unsecured Protected Health Information; Final Rule, effective on March 26, 2013 and reached the following conclusion.

☐ **Breach notification is required.** <Name of organization> concludes that notification is required because the assessment above supports that there is greater than low probability that the PHI has been compromised.

☐ **Breach notification is not required.** <Name of organization> concludes that notification is not required because the assessment above supports that there is a low probability that the PHI has been compromised.

**Scope of Notification** (*Note: If more than 500 individuals OCR and Media Notice is required*)

### **Other corrective action(s) required:**

- DIT corrective actions(s)

- Manager(s) responsible for implementing corrective action:

Date corrective action should be delivered:

- Date of corrective action; confirmation by the HIPAA Compliance Officer

### **HIPAA Compliance Officer Analysis:**



# HIPAA Compliance Program

## Breach Notification Risk Assessment Tool

### Preventive action(s) required:

Describe who, what, when and how the preventative action(s) will be carried out:

# HIPAA/HITECH Decision Tree to Determine Whether Breach Notification is Required

