Guide to Payor - Virtual First Care (V1C) Contracting

a resource produced by

Virtual First Care Coalition





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OVERVIEW OF THE GUIDE TO PAYOR-V1C CONTRACTING

Scope of the Guide to Payor-V1C Contracting

The V1C Coalition by DiMe developed this Guide to Payor-V1C Contracting to establish a common baseline for Payor-V1C contracting interactions. This document addresses the need for fit-for-purpose approaches to these agreements that incorporate the unique features of V1C solutions. It details all the sections traditionally included in a payor-provider contract and contemplates wraparound services and features that wrap around these providers as components of V1C.

Target Users

The Payor-V1C Contracting Toolkit was created for innovators, leaders, and decision-makers in V1C companies and payors considering including V1C solutions.

Within V1C companies, the following audiences will find this resource particularly useful:

- CEOs
- Commercial leads
- Business development functions
- Sales teams
- Legal counsel (internal and external)

At payor organizations, various groups will benefit from this resource:

- Innovation groups charged with piloting and integrating V1C at larger companies
- Chief Medical or Health Officers at smaller regional plans
- Networking
- Procurement officers
- Product teams responsible for contracting and integrating new providers onto the plan
- Legal teams handling contracting with novel V1C solutions

PAYOR-V1C CONTRACT FUNDAMENTALS

The definition of V1C solution providers as HCPs is foundational to this guide. Just because a V1C provider uses software to support care delivery does not mean the V1C solution is a vendor with a software-as-service model. V1C solutions are complete solutions that support a person in taking all necessary steps in their health journey.

Specifically, V1C organizations deliver:

- "Health care" as defined in <u>federal regulations</u>
- Care as a "provider" as defined in federal law, including either:
 - o A provider of medical or health services or
 - Any other person or organization who furnishes, bills, or receives reimbursement for health care in the normal course of business.

V1C solutions are, therefore, Health Insurance Portability and Accountability Act (HIPAA)-covered entities with additional implications:

- V1C solutions own their patient's data. Just as between a payor and any provider, information collected by a V1C solution from individuals who receive care within their platform is owned by the V1C and not a payor.
- V1Cs have the same obligations toward their patients as brick-and-mortar providers do.

Throughout this toolkit, you will see references to payors. We define a payor as the person, organization, or entity that sets service rates collects payment, processes claims, and pays claims associated with healthcare services administered by a provider. Payors include health plans that may represent their populations or those populations of self-insured employers, as well as government-funded healthcare programs like Medicare and Medicaid.

Depending on the services provided and the state(s) in which it operates, a V1C organization may follow several different organizational models, including separating duties between a professional corporation (PC) that provides health care services to patients and a Management Services Organization (MSO) that provides support services to the PC. If the V1C entity follows this structure, contracts with payors should avoid terms that interfere with the V1C company's sharing responsibilities between the entities that make up their offering.

If the V1C service has a structure that includes a PC and an MSO, the provider contract is typically between the PC and the payor.

HOW TO USE THE GUIDE TO PAYOR-V1C CONTRACTING

This document is organized by the two critical parts of a contract:

- 1. The <u>Contract Body</u> lists sections routinely included in every contract. Some sections adhere to standard approaches, while others should contain language unique to V1C services.
- 2. The <u>Contract Exhibits</u> may or may not apply to a particular V1C solution and will, therefore, be mixed and matched as applicable to a specific relationship. Readers should discern this for themselves.

Note that sections are presented in a logical order but may be reordered as appropriate for a given agreement. This document should not be considered legal advice. You should seek appropriate counsel for your situation.

As each section is discussed, contracting practices are denoted as 'ideal,' 'acceptable,' and 'to avoid,' providing end users of these agreements with a spectrum of opportunities and practices to avoid. In specific instances, the text provided is an example for you to consider as you craft your agreements.

Another feature of specific sections with unique V1C considerations is the discussion of Phase 1 and Phase 2 of a collaboration. Recognizing that many new V1C-payor relationships seek to balance risk, the partnership may start small by generating V1C service data in a given payor population before scaling more broadly.

- Phase 1 recommendations are intended to serve as critical aspects of an agreement that must be in place when the relationship starts. Phase 1 is usually bound by a specific period of time or number of members. When that bound is reached, both parties can evaluate financial and clinical performance to inform the next phase.
- Phase 2 contemplates a larger, scaled engagement where additional measures and considerations in the contract may be appropriate, and adjustments based on the value created in Phase 1 may be applicable. We have noted where differentiation between what might be needed at the outset differs from an agreement to support a fully scaled solution.

Overall, the suggestions included in each phase are recommended but not required — ultimately, what's suitable for the relationship will be decided on a case-by-case basis.

Finally, some sections include sample language that refers to a specific point made in that section to model for readers how that section may be crafted in their agreements. Ultimately, this is a suggestion for consideration and is not intended as legal advice or as appropriate for your specific situation.

Throughout this document, providers of V1C services are referred to as V1C services. V1C services include the management groups of V1C companies that sometimes perform on behalf of themselves and affiliates that comprise their organization (such as one or several medical practices). As discussed above, other V1Cs may provide services under protocols that do not require a PC for the applicable healthcare professionals.

Individuals eligible for and receiving V1C are referenced two ways in this document. A member or plan member refers to an individual with healthcare coverage through a payor. A participant or V1C participant refers to someone who has signed up for a V1C service. Members of a health plan who sign up for V1C services are both members and participants — we've tried to use the appropriate language for the setting the individual finds them in throughout (e.g., when outreach is being conducted to invite someone to a V1C service, the outreach is to a plan member; reporting on individuals enrolled in a V1C service is on participants).

Finally, italicized terms throughout the document are fully defined in the <u>Glossary of Terms</u>.

CONTRACT BODY

The sections included in the contract body are general governing principles of the provider/payor relationship and should be applicable across multiple statements of work. They are not intended to state details of a particular phase of engagement between the two parties; they are more focused on setting up the optimal relationship throughout interactions. The order in which the body sections appear is not intended to be recommended—that decision is up to the end users and contract developers in a particular deal.

The contract body sections should be tailored to the unique aspects of the V1C approach and include language matched to the novel nature of these solutions. Each of the following sections indicates traditional clauses typically included in that section and additional features that should be explicitly included to contemplate V1C.

Contract Body: Termination Rights

This section focuses on how and when each party may end the agreement/services being provided, setting provisions for the Termination Notification Period, Runout Period, and Maintenance of Records/Duty of Care. This section should not include any terms about how data is handled at termination—this is included in the Contract Exhibit: Data. Also, project-specific transfer of care obligations will be covered in Contract Exhibit: SOW Definition of Services.

V1C CONSIDERATION: Termination Rights

This section should include:

- There may be technical differences between provider-only contracts and V1C solutions. For example, what happens to the data the payor has supplied to the V1C if the V1C provider-payor relationship ends?
- Any rights that a payor may need to retain access to V1C solution software beyond the scope of their contract with a V1C provider, if applicable.
- Runout provisions to avoid disruption of care/continuity of care.

	Phase 2>
[no timing-specific implications for content are suggested in this phase]	In Phase 2, an evergreen clause should be included, allowing for auto-renewal of the agreement. This can be indefinite or a 1-2 year auto-renewal at the end of the contract term.

Contract Body: Assignment of Agreement or Obligations

This section sets forth the circumstances under which each party can assign obligations to a third party. The language should be based on that of a traditional provider contract.

V1C CONSIDERATION: Assignment of Agreement or Obligations

This section should include:

- Where the V1C service is the management group and has affiliates (e.g., one or multiple medical practices), the legal concept of the affiliate.
- V1C management group should be given the right to manage the performance of obligations across the entire organization while accounting for the corporate practice of medicine not being one legal entity.

- Language about what happens if either company is acquired, including continuing the contract obligation without disruption.
- Generally speaking, nothing in this section should be construed as preventing a V1C service from delegating the performance of any element of this agreement to an affiliate (or member of V1C's "medical group").

Contract Body: Business Associate Agreement

Where V1C services and payors are both HIPAA-covered entities (as is typically the case) and their interactions and data exchanges fall within the stated HIPAA uses of Treatment, Payment, or Operations (TPO) definition, many contracts won't need a business associate agreement (BAA). However, there are some unique situations where a BAA is necessary — specifically when data is being exchanged between the two parties for a use unrelated to TPO. Two key moments in the member/participant experience where one or the other party may prefer to use a BAA are:

- 1. A payor's disclosure to the V1C of a member list so that the V1C can tell individuals they are eligible for participation in the V1C service or,
- 2. A payor is sharing a member eligibility list with a V1C solution to enable authorization for coverage of a qualified V1C participant.

Recruitment for a research project needing approval by an Institutional Review Board (IRB) is another instance where a BAA may be required.

In most cases, a BAA should not be necessary because the V1C and payor each operate as a covered entity, using Protected Health Information (PHI) for treatment, payment, and operations purposes. If a BAA is needed, the parties should justify it by explicitly defining the scope of its activities and providing a sound rationale for why it is necessary. The BAA is typically appended as an exhibit or signed as a separate document by the two parties. The contract then includes this section to state general principles on how that exhibit or standalone document will be integrated into the relationship.

V1C CONSIDERATION: BAAs

• If a payor shares a promotion or eligibility file with a V1C service, and the V1C comprises a PC and an MSO, the master contract with the payor typically exists between the V1C PC and the payor. Still, it sometimes is between the V1C MSO and the payor.

- For promotion activities, the MSO typically conducts that activity, and the contract should appropriately contemplate the necessary arrangement (e.g., a BAA may be needed to cover the MSO if the contract is between the V1C, PC, and the payor).
- If this is the case, this section will reference that arrangement.

IDEAL ★★★

No BAA is needed because the payor and the V1C solution are each covered entities, using and disclosing PHI to each other for treatment, payment, and operations purposes.

- The payor retains Eligibility data (with V1C pinging the eligibility database as needed).
- V1C is conducting outreach to invite a plan member to join their service with messaging that includes features of the solution for a given disease and explicitly does not mention the payor name and coverage of that service by the payor. A provider can <u>legitimately get a list</u> of people from a payor and then do outreach as the provider's TPO [(c)(4)(i)] as part of healthcare operations.

Select cases where a BAA may be needed and conventionally is in place, include:

- V1C is conducting outreach that references the payor name and coverage of that service by the payor to invite a plan member to join their service.
- Data will be exchanged to support program evaluation for purposes outside of TPO (see <u>Data section</u> for more details on what may qualify here).

ACCEPTABLE ★★☆

A BAA is needed to cover any promotion activity conducted by a V1C service.

A BAA is needed to cover eligibility data being transferred from the payor to the V1C service because no payor exchange exists.

Phase 1	
BAA as needed for eligibility and promotion	BAA will likely need to be modified if V1C intends to conduct a Return on Investment (ROI) analysis with data disclosed by a payor. This area can be complex depending on what member data may be included and who the intended recipient of that payor data is. Per Contract Exhibit: SOW Program Evaluation and Contract Exhibit: Data sections, the parties should fully define the goals of the ROI analysis and then consult with counsel to structure the agreement appropriately.

Contract Body: Publicity

This section focuses on each party's use of the other party's brand and name. It consists of standard marketing language around rights and obligations that typically require written permission from each party to use the other's likeness.

V1C CONSIDERATION: Publicity

An additional clause related to the payor's concerted effort to make information available regarding V1C services and offerings may be appropriate here. It may include examples such as promoting the new service, care, access, or additional benefits offered to the payor's members, customers, employees, defendants, etc. This gives V1C services some assurance and commitment from payors that their payor counterparts will support the adoption of their offering.

Sample Language: "Either party may publicize its relationship with prior written approval from the other party. Either party may also offer the other party as a reference and/or use case to prospective customers and partners and use the other party's logos and branding in customer lists, websites, and other materials advertising the other party's use of the Services."

Contract Body: Payment

This section provides the primary term governing payment between the two parties. A <u>Guide to V1C Payment Models</u> has been developed to support V1C companies and payors in determining the best-fit payment model for their relationship.

V1C CONSIDERATION: Payment

- A V1C service is a provider and should be <u>compensated at a fair payment rate</u> for the services performed that also considers the ongoing investment necessary to ensure these virtual first platforms are continuously maintained and seamlessly updated and services can continue to expand as needed.
 - Claims are the preferred billing mechanism for whatever payment model is used, enabling claims data to be used in analysis and tracked explicitly.
 - Some exceptions exist to using claims where invoicing will be necessary (e.g., if the contract starts mid-plan year).
- Payors should consider V1C provider cash flow needs when setting payment timelines and adhere to industry best practices of terms payable net 30 (ideal) or net 45-60 (acceptable).

The following sections in the contract body should not deviate significantly from the approach taken when negotiating an agreement with a brick-and-mortar provider, and so are not covered here:

- Provider Rights and Obligations
- Payor Rights & Obligations
- Liability Indemnification & Risk
- Effective Date
- Applicable State & Local Laws
- This Agreement Supercedes All Prior Agreements
- Force Majeure
- Disclaimer of Waiver of Performance
- Unenforceable Parts of the Agreement (Severability)
- Confidential Information (related to information exchanged about the two parties and businesses themselves. Information exchanged in the specific project the two parties will do together, including data sharing, is handled separately and in <u>Contract Exhibit: Data</u>)

CONTRACT EXHIBITS

Exhibits are meant to support unique aspects of a given payor-V1C relationship. They are intended to apply broadly to the overall relationship between a V1C service and a payor, with the exception of a statement of work (SOW) exhibit, which gets into the specific details of a defined engagement (e.g., Phase 1 or Phase 2 of work). As in the body sections, the order in which the exhibit sections appear is not intended to be prescriptive — that decision is up to the end users and contract developers in a particular deal.

Contract Exhibit: Data

This exhibit covers what project-related data each party will collect, what data will be shared between parties, file standards for sharing, and security mechanisms in place to protect data. Data sharing is always guided by whether data is being shared for use in the TPO of the payor's organization or the V1C service and, therefore, whether that data exchange is a part of each party's HIPAA-covered status. Where data is not covered under a party's TPO or where the recipient of participant data is not a HIPAA-covered entity (e.g., fully insured employers), additional documentation around appropriate permissions to access, security practices, and other agreements (such as a BAA or patient consent) may be necessary.

Data use is a primary focus of this section. Generally, data use falls into these categories, and the contracting parties will need to discuss if and how data will be exchanged in each instance:

Data Type	Data Use	Sample Data Flow
Outreach	To invite members to join a V1C service	Payor copy of member name, email, address, and/or phone will be used by the payor for outreach or shared with V1C service to conduct outreach. Data sharing with the V1C solution ideally excludes member numbers for security purposes. This data may be collected again by a V1C service in the onboarding process.
Member Eligibility	To support ongoing checks of member eligibility for coverage of care by the payor at the start and for the duration of an individual's participation in a V1C service	The payor houses the member's name, number, and eligibility status. Data is made available to the V1C service either through a platform that can be accessed by the V1C service to determine real-time eligibility (through a 270 ping)

		or through a monthly eligibility report transmitted to the V1C service. The V1C service owns data on the result of the eligibility check (271 responses), as it does with any provider.
Program Delivery	To support care coordination and payor benefit personalization	Payors may share claims data and other clinical information they store about V1C participant-related medical care provided outside of a V1C solution. V1C services store PHI in their Electronic Health Record (EHR), including clinical, test results, or other information about a participant and the care provided by the V1C service.
Program Participation & Outcomes	To measure enrollment, engagement, and health outcomes	As part of program outcome analyses, payors may share claims data and other clinical information about a V1C participant related to medical care provided outside of a V1C solution. V1C services may share enrollment data, EHR data (de-identified as required by the receiving entity's HIPAA coverage status), and engagement data. Sharing this data doesn't change ownership of PHI or the proprietary nature of the data.
Program Evaluation	To measure non-clinical outcome variables of V1C performance, such as costs and member satisfaction	Payors may share claims or member satisfaction data, and V1C services may share EHR data, participant engagement, or satisfaction data. Again, ownership resides with the originating party, and any publication or Intellectual Property (IP) would be assigned according to data originating from a single party or shared by both parties. The identifiability of the data disclosed is defined by HIPAA rules.

This section will cover where data will be exchanged, how it will be shared, each party's rights to use another party's data, and data security requirements. Finally, it will include agreements on the continuity of TPO data availability following contract termination.

V1C CONSIDERATION: Data

Since both parties are covered entities, <u>requests for data sharing</u> from both parties should be respected where that data (including PHI) is deemed necessary and appropriate for the conduct of each of their TPOs, consistent with:

- Guidance from the Office for Civil Rights (OCR) on the <u>exchange of PHI for</u> the other party's health care operations and
- The Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS) <u>rules and standards for exchange</u> (for example, the data available in the U. S. Core Data for Interoperability standards for certified EHRs and payors). V1C owns payor member data generated on their platform since the V1C platform is a medical record, and the provider is obligated to own and manage that.

IDEAL ★★★	TO AVOID ☆☆☆
General	
Security requirements should follow traditional provider security expectations — System and Organization Control (SOC) 2 Type II Report or HITRUST should suffice for non-TPO data.	Additional security requirements mandated by payor beyond SOC 2 and HITRUST — exposure to member information is low, and given that V1C is a covered entity, they should be trusted.
Agreements and projects should proceed if V1C service is still in the process of obtaining security certifications, as long as reasonable faith effort and progress are being made.	Requests/requirements to provide a SOC 1 (either Type I or Type II) report. SOC 1 is related to financial controls for publicly traded companies. This should not be required unless a V1C service is part of a publicly traded company.
Usage of Fast Healthcare Interoperability Resources (FHIR) standards for seamless Application Programming Interface (API) integration.	Payor ownership of V1C data — V1Cs are providers and, like all doctor's offices, are the "owners" of all patient data stored in EMR upon establishing a care relationship. (Payor retains ownership of marketing data since this is before establishing the care relationship.)
	Data blocking — data should be allowed to flow bi-directionally when legitimate TPO justification exists.
Program Evaluation	
Where the V1C-payor is undertaking	Arbitrary assumption that consent is/is

activities primarily intended to contribute to general knowledge beyond TPO, routine treatment, and internal use of V1C service data for analyses, consent from V1C participants for research uses of data will be needed. not needed. OCR/ONC fact sheet on the exchange of data and the OCR FAQ on what research should be considered.

Examples include activities, tests, assessments, and routine care provided by a V1C solution, asking patients to support research goals, and engaging external parties (such as researchers or research institutions) to conduct studies.

ion for phase 2 is that the V1C If the V1C service is performing

If the vision for phase 2 is that the V1C service is performing non-TPO activities, include details for initiating necessary security assessments and processes to set up phase 2.

If the V1C service is performing non-TPO activities, the SOC 2/HITRUST security assessment, whether it is in process or completed, should be contemplated.

Contract Exhibit: Subcontractors

This exhibit focuses on subcontractors and should be included where the contracting entity has subcontractors involved in delivering work. This section then details how those subcontractors will be selected, qualified for their roles, and responsible.

V1C CONSIDERATION: Subcontractors

Subcontractors of V1C solutions generally fall into three categories. Depending on which functions they will serve, one or several of these sections may be appropriate.

- Consultants or gig workers may be on 1099 (independent workers who
 receive non-employment income). Contracts for these individuals may
 specify required workforce controls, such as background checks or
 verification of required licensure.
- Vendors and other service providers are subcontractors, such as technology

companies, cloud service providers, data processors, or other third parties supporting V1C's functions (especially technology). These subcontractors are the V1C's business associates, and the V1C should have BAAs in place with them. Contracts may specify requirements around liability insurance.

• If the V1C solution operates as a PC and affiliated MSO, that entity should be referenced here. The V1C PC is responsible for ensuring that this contract does not interfere with the MSO's ability to perform necessary functions.

TO AVOID ☆☆☆

Payor approval for subcontractors — HIPAA-covered entities should be trusted to select and perform their duties without payor approval.

Strict BAA pass-thrus. V1Cs often have minimal ability to negotiate changes to service provider BAAs (especially BAAs from large cloud service providers).

Contract Exhibit: Credentialing & Verification of Certification and Licenses

This exhibit pertains to V1C solutions that include formally credentialed medical professionals and/or care team members with professional licenses and certifications that need to be maintained but may be outside the scope of a credentialing organization. Including one or both of these should be tailored to each agreement.

Credentialing of Medical Professionals

For V1C services that rely on select medical professionals who offer clinical expertise, this section will highlight how those clinicians will be credentialed or verified following the legal or policy stipulations for their professional function. Where clinicians need credentialing, this section will include who will manage credentialing, how that credentialing process will take place, and how confirmation that they are eligible to practice in a given state will be documented.

V1C CONSIDERATION: Credentialing

The goal is to ensure that the V1C service is following guidance on provider credentialing from the following:

National Committee for Quality Assurance (NCQA),

- Utilization Review Accreditation Commission (URAC), or
- Accreditation Association for Ambulatory Health Care (AAAHC) (worksite clinics).

Determine the most efficient way for V1C to acquire credentials, given their stage and capacity. This may include: V1C as a delegate of payor V1C outsourcing this function to a Credentials Verification

Organization (CVO)

 V1C using a payor's credentialing process is especially common for earlier-stage V1C services but not as well suited for scale and speed over time

Advocate for innovation in credentialing over the long term, considering solutions such as the adoption of interstate licensure compacts, interstate licensure through a national credentialing approach, or a centralized repository for the most up-to-date info on credentials that could be widely accessed.

TO AVOID ☆☆☆

Long wait times for the credentialing process at the payor due to credentialing team confusion about why someone is being authorized in two states — at the outset, the payor should be prepared to set context internally for these submissions and advocate for V1C in the credentialing process to smooth any concerns or delays around V1C provider location (e.g., why one Doctor of Medicine (MD) is being credentialed in multiple states).

Allow work to start before the credentialing process is complete, given the low risk of virtual providers.

[no timing-specific implications for content are suggested in this phase]

Verification of Certification and Licenses

For some care team members included in V1C services, verification of a professional certification or license is appropriate. This section should include how that verification will occur and what aspects will be covered in these cases. This may include confirmation that the license/certificate is active, absence of debarment, criminal background check, review of credentials, etc.

V1C CONSIDERATION: Verification of Certification and Licenses		
IDEAL ★★★	ACCEPTABLE ★★☆	
V1C service warranting or representing that V1C will maintain up-to-date certification and licensure, with no ongoing reporting to the payor required	V1C maintains outside approval of their credentialing process, like URAC, for example	

Contract Exhibit: Audits

This exhibit covers the process of payor review of V1C service practices to ensure they are compliant across a diverse set of domains that may include finances, security, billing, and coding and/or Health Plan Employer Data and Information Set (HEDIS). The contents of this section should include a clear description of the audit process, timeframes and maximum frequency of audits, timeframes for V1C service submission of documents and payor responses to them, a process for appeals, and limitations on extrapolations if issues are found.

V1C CONSIDERATION: Audits

- Audit requirements for V1C services should be no more than those of brick-and-mortar providers and, more broadly, what the law requires.
- Payors and V1C services should consider the intricacies of audits of a virtual care model with distributed personnel and structure of care provision. Contract language should be tailored to align with the infrastructure that exists in the V1C service. In developing this section, payors should be attuned to the fact that V1C services are virtual, which means that they don't have a physical site of care for auditing, and gathering necessary personnel across locations and time zones may not be as easy as what is traditionally the case. Business teams at payors may need to be involved in advocating for this with their legal teams.

Contract Exhibit: Publication Rights

This exhibit details each party's rights to publish research or share public reporting related to the relationship. It includes details such as each party's right to publish, the review process before something is submitted or published, and any rights to block or modify publication (primarily related to IP that may be disclosed in the

published material). This section naturally follows many of the terms established in the <u>Data Exhibit</u>.

This exhibit should be included in all phases of all contracts, even if specific publication plans aren't envisioned at the time of contracting, to contemplate the possibility that an unforeseen opportunity may arise. Both parties should have the flexibility to respond to it.

V1C CONSIDERATION: Publication Rights

Publication rights should follow data rights, whereby research on data wholly owned by a given entity should be freely publishable without the other party's permission. Where data is sourced from both entities, agreements about the opportunity to review, provide input, and obtain permission to publish may be appropriate.

	Phase 2>
At least include a boilerplate stating a generic position that will be in place until and unless the parties agree to something else, which would then be documented in a new or revised exhibit.	Given the field's early stage, the best practice is to publish or share a report on the collaboration's results to engender field-wide learning.

Sample Language (Phase 1 Boilerplate):

"Each party will have the right, at their discretion, to release information or to publish findings, conclusions, writings, or material resulting from clinical research undertaken with data collected or created from [THE PROGRAM]. The party initiating the clinical research (the "Sponsor") will be solely responsible for ensuring that any and all necessary informed consent is collected from participants or that a waiver has properly been obtained from a competent Institutional Review Board in compliance with HIPAA rules. In the event that any clinical research undertaken pursuant to this section results in the publication of results, the Sponsor will furnish the non-sponsor party with an advanced copy of any proposed publication prior to the proposed publication date and grant the non-sponsor party the opportunity to review and provide comments on the published materials and, upon the non-sponsoring party's request will redact any information that the non-sponsoring party perceives to be confidential to the non-sponsoring party. Sponsor agrees to consult with the non-sponsor party on using the non-sponsor party's trademarks, trade dress, or other intellectual property and will comply with any brand usage guidance provided by the non-sponsor party. However, the non-sponsor party agrees that it will not unreasonably withhold permission to name the non-sponsor party or use its trademarks in the published materials."

Contract Exhibit: Statement of Work

This exhibit contains the project-specific details of the two party's work together on a particular engagement. Because there is so much content in the work plan that is unique to V1C, we've broken this one exhibit down even further into parts, including:

- Definition of Services
- Outreach
- Eligibility Verification
- Pricing
- Coding (if applicable)
- Referrals Outside of the V1C Solution
- Program Participation & Outcomes
- Program Evaluation

Contract Exhibit: SOW - Definition of Services

This section of the statement of work (SOW) describes the details of the V1C solution being deployed in the project, including its components.

V1C CONSIDERATION: Definition of Services

This section may include the following:

- The delineation between services offered, where multiple offerings or service lines will be included
- Details of how the service will work for a participant and the participant's experience on the V1C service (by service line, if applicable)
- Any exclusions from the scope of the service offering, such as a V1C service that provides prescribing but where the cost of the drug itself is not included
- Details on any common medications or procedures that may be prescribed or performed by the V1C solution that are expected to require prior authorization
- Any customized configurations or implementation planning that will be required
- Project-specific plans for the use of name or brand are contemplated
- Service Level Agreements (SLAs) where an SLA is a selling point/vital feature of the V1C solution. If an SLA is not a critical feature of the V1C solution, the exact expectations of service level performance applied to brick-and-mortar healthcare should be applied here.
- Commitments around milestones or stage gates and associated timelines

Transfer of Care Obligations should also be covered in this section, including:

- Provisions around V1C services transfer patients to brick-and-mortar facilities for care that cannot be administered virtually.
- Where the V1C service is contracted to provide for an episode of care, how will V1C services transfer participants back to their originating care setting?
- All contracts should include terms around timelines for the V1C service transition period for care for a participant who is no longer a covered member by the payor, including the number of days of care coverage and any other terms around the transition of care and this time period. Costs related to this transition period should be outlined in the SOW Pricing section of the Contract Exhibit: SOW Pricing section.

	Phase 2>
Define the end of the agreement as the time or number of members in service.	[no timing-specific implications for content are suggested in this phase]
State as much as is known about plans for the timing and structure of SOW for Phase 2.	

Contract Exhibit: SOW - Outreach

This section of the SOW covers how outreach to payor plan members will be conducted. It should exclude outreach data, as defined in the <u>Contract Exhibit: Data</u> section.

V1C CONSIDERATION: Outreach

This section should include:

- What channels (email, mail, phone, text messages, etc.) may be appropriate?
- Who will initiate the outreach? Will payors contact their members, or will V1C service be provided with a list to conduct outreach?
 - Determining who will be doing the outreach is essential. The decision hinges on a few key factors: what the payor review process is for promotion communications to members, payor requirements around security and verification, and what rules apply to the data being used (HIPAA, state privacy law, Federal Trade Commission (FTC), etc.) as

well as company preferences of each party. Further, when outreach methods to be used are also regulated by the FTC and The Federal Communications Commission (FCC), for example, robocalls or SMS/Texting, the parties should agree on how provisions in those laws around health care apply to the relevant activity and which entity will be responsible for compliance.

- Who will be responsible for crafting outreach messages?
- What is the timeline and cadence for messaging?
- Planned guidelines for training to support promoting the V1C service to qualified members at the outset and over time. Training should occur at the payor (i.e., customer service, sales), as well as for third-party partners of the payor's plan, such as primary care and navigation players on the V1C service offering to ensure "front doors" where the member may first inquire about covered services are educated and equipped to share V1C services with plan members.
 - Training and education plans should also be specified for other V1C services that may refer to the contracting V1C service and brick-and-mortar providers who may refer to the V1C solution.

IDEAL ★★★	TO AVOID ☆☆☆
Messaging and deployment should follow outreach and email tracking best practices to ensure effective messaging and embedded tracking.	Not planning for any active outreach — people won't find these solutions without some promotion.
Enable traffic from all channels (referrals, physician directory listing in all applicable zip codes, third-party partners, etc.) to the V1C solution.	The payor outreach team is drafting outreach without V1C input/guidance.
Define payor and V1C service promotion review processes required to approve member outreach, including timelines and SLAs.	

If V1C service is doing outreach:

IDEAL ★★★	ACCEPTABLE ★★☆	TO AVOID ☆☆☆
Conventionally, V1Cs getting promotion data requires a BAA (when it is seen as the TPO of the	Co-branding of outreach with V1C messaging templates that include space for the payor logo.	Payor requests for complete white labeling, payor branding, and colors — V1C services

payor, not the TPO of the V1C).	need to build brand recognition, and relationship and technical
Clarify the responsibilities of each party (generally), which is responsible for testing, approvals, and frequency of meetings to monitor/revisit.	customization are expensive and time-consuming.

If the payor is doing outreach:

ACCEPTABLE ★★☆

Commitment to a bare minimum number of promotion opportunities in a given timeline (to prevent payor blocking outreach, which results in less adoption of/revenue for V1C).

Contract Exhibit: SOW - Eligibility Verification

This section of the SOW focuses on verifying eligibility on the payor's plan for a potential participant on a V1C service and ongoing eligibility verification throughout a participant's care. This section does not include how eligibility data is accessed, which is contained in the Contract Exhibit: Data section.

V1C CONSIDERATION: Eligibility Verification

This section should include:

- Defining criteria for the eligible population (by service line if applicable)
- Specific data that will be used to determine eligibility
- The process for determining eligibility throughout participant engagement with a V1C solution
- Where applicable, the process for prior authorization if it is necessary to determine whether a member's plan covers the cost of the V1C service.

IDEAL ★★★	ACCEPTABLE ★★☆	TO AVOID ☆☆☆
Real-time member	Flat eligibility file	One-time or less than
eligibility data access to	transmitted through a	monthly data transfers of
support ongoing	Secure File Transfer	verified member
verification provided on a	Protocol (SFTP) solution,	information for eligibility

HIPAA-covered, payor-managed platform (i.e., via 270/271 or Healthcare Effectiveness Data and Information Set (HEDIS).

Provide a clear definition of eligibility: It may be based on clinical features, demographic characteristics, existing diagnosis (in codes), a referral from another provider, etc.

To broaden the catchment area/eligible population to match V1C licensure, the whole state should be included in location definitions of the eligible population.

shared monthly to align with the billing cycle.

checks — V1C is often longitudinal, requiring ongoing member verification.

Contract Exhibit: SOW - Pricing

This section of the SOW outlines how the payor will pay for the V1C solution and is an exhibit that should be included in every agreement. It does not include specifics on payment coding, which will be handled in <u>Contract Exhibit: Coding</u>.

Contracting parties can reference the <u>V1C Coalition by DiMe Guide to V1C Payment Models</u> to determine the best-fit payment model appropriate for a particular SOW.

V1C CONSIDERATION: Pricing

This section should specify:

- What payment model is being used, what is the cost-sharing arrangement (across payor, provider, and member/participation, where applicable), and what are the pricing tiers (where applicable)?
- What's included in that payment (e.g., the components of V1C)?
- The billing process to be used (invoice or claims).
- A clear definition of engagement, or what counts as one billable participant,

is typically defined as a particular moment of the V1C process a payor's member will reach to count as billable.

- Performance guarantees, service level guarantees, and cutoffs for performance bonuses/credit (including details on how the payment/credit process will work if goals are hit or missed).
 - It should also clearly define which party is capturing this data, the process being monitored, and how missing data will be handled in accounting for performance and service levels.
 - o If/as a V1C is at sub-risk, specify attribution of costs as well.

IDEAL ★★★

Per Participant per Month (PPPM) or Episode of Care model or an alternative payment model that assigns at least some risk and potential upside to the V1C solution.

Where possible, V1C tracks a performance guarantee grounded in clinical outcomes and/or literature for their cohort and informed by a baseline measure derived by the payor. Admissions, discharges, and transfer data may be helpful here.

If V1C has evidence and a track record trusted by the payor — phases 1 and 2 should be value-based and include bonuses/deductions based on set performance/service levels.

There is no charge to the member for participating in the core service.

Care transition costs are paid for up to 90 days by

ACCEPTABLE ★★☆

If V1C is less mature and/or the payor requires data in their population before they can go at risk — then phase 1 can be bundled fee-for-service (FFS) with a transition in phase 2 to more shared risk and bonuses/deductions based on performance/service levels.

In some plans (e.g., high deductible health plan (HDHP) where co-pay is required), providing V1C without a member fee all the time won't be possible.

The payor doesn't cover care transition costs (but V1C service continues to provide continuity until the participant is transitioned).

TO AVOID ☆☆☆

Ill-defined engagement metrics for what counts as participant/dropout, milestones, or pricing tiers have led to confusion and breakdowns around already complex billing processes.

Including penalties for underperformance without a bonus for success fails to provide an appropriate upside for positive outcomes.

Shared savings models that don't explicitly state how savings will be calculated.

Restricting a V1C service from offering guidance on what's clinically indicated for the patient may result in V1C selling add-ons to the member (e.g., a V1C-developed connected device or additional exercise program) and may or may not be a covered cost by the payor.

the payor (unless V1C
service breaches the
contract).

contract).	
Phase 1>	Phase 2>
PPPM or Episode of Care bundled payment for services - OR - It uses a payment model that assigns some risk and potential upside to the V1C solution.	Review the value created and adjust the payment model based on this information. This could lead to adjusting the existing model or a transition to a capitated/bundled model.
Limited to a set period/number of participants to generate necessary evidence to support scaling decisions in a payor's population	

Contract Exhibit: SOW - Coding

This section of the SOW outlines how coding to process claims-based payments will be aligned to the payment model selected in the <u>Contract Exhibit</u>: <u>Pricing</u>. This exhibit should be included in any contract where medical coding and claims will be the basis for reimbursement for a V1C solution.

V1C CONSIDERATION: Coding

• Determine what types of codes and specific codes will be used for billing. It's essential to recognize that not all payors are using all codes, so V1C services may have to partner with a payor in implementation to navigate to alternate codes or get codes added so they can use them.

IDEAL ★★★	TO AVOID ☆☆☆
Identify a set of codes that clearly reflect all services being provided, and that can successfully be approved in the claims submission process Coding claims should be submitted via clearinghouse (in-house or 3rd-party familiar with V1C services) to ensure success in the approval process	Payors use administrative budgets to pay for costs that should be coded as medical spending. This practice is prevalent in the per-member per-month (PMPM) payment model Not using a clearinghouse to submit claims — leads to an increased rate of rejected claims, which results in added work, delays, and expense in the billing

Future state: collaborate with the field process on a set of V1C proposed codes that align to the unique components of V1C-specific offerings	S
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Contract Exhibit: SOW - Referrals Outside of the V1C Solution

This section of the SOW describes the payor's referral preferences for any referrals the V1C service may need to make. This section should be included in any SOW related to a V1C service coordinating care with other entities.

V1C CONSIDERATION: Referrals Outside of the V1C Solution

This section should specify:

- How second opinion requests should be handled.
- Preferences for how a specific service not being available in-network should be handled.

IDEAL ★★★	ACCEPTABLE ★★☆
Define payor preferences for how they want the contracting V1C service to refer to other V1C services, in-network providers, or the most cost-effective resources	Provide access to a broader provider directory

Contract Exhibit: SOW - Program Participation & Outcomes

This section of the SOW outlines measuring enrollment, engagement, and health outcomes of V1C service participants. This exhibit should be included in all phases of all contracts.

V1C CONSIDERATION: Program Participation & Outcomes

This section should specify:

Member outcomes that both parties want to track over time, including what

will be captured in data files and reports.

• What reports will be shared, and on what schedule to track progress toward target milestones, outcomes, and goals around the V1C service?

IDEAL ★★★

V1C provides a "participation file" (sensitive that PHI may need to be removed depending on the audience, e.g., fully insured employers), accompanied by quarterly review calls, to discuss enrollment data, engagement data, and aggregate (not individual) clinical/economic outcomes.

Determine a V1C schedule for sharing aggregated clinical data and aggregated financial outcomes reporting on various enrollment, engagement, and outcome data (monthly, quarterly, and/or annually). In select cases, weekly reports may be helpful and justified.

Set a cadence for regular check-ins to discuss any trends or changes.

Contract Exhibit: SOW - Program Evaluation

This section of the SOW goes beyond the program outcomes to specify the non-clinical outcomes of the project. This may include variables such as cost and member satisfaction. This section specifies what analyses will be conducted, who will perform the analysis, at what time/participant volume, and the cutoff point for claims to be included. It also specifies any patient consent required to collect non-TPO data. Finally, this section will also provide details on what will be published and who is responsible for the publication in a project-specific SOW.

V1C CONSIDERATION: **Program Evaluation**

- Should contemplate consent for select analyses where research conducted required IRB review. Generally, this includes participant engagement with added tests, assessments, and activities outside of what would traditionally be required for them to receive care from the V1C service, where individual-level data is being reported on or published or where participant data is being shared externally with a research partner.
- De-identification practices for audiences not defined as covered entities should be followed when sharing and reporting on data.

IDEAL ★★★ ACCEPTABLE ★★★ TO AVOID ☆☆☆

Upfront commitment from both sides to do program evaluation

The two parties collaborate on work with a 3rd-party to conduct the data analyses to ensure the most rigor and unbiased analysis

V1C service to collect participant satisfaction data

Either party has the right to conduct independent research with any member/participant in V1C

Both parties keep one another informed of independent research design and findings Denying V1C the right to conduct research in their population — should have the same rights as brick-and-mortar providers

Payor conducts program research without discussing methodology or assumptions with V1C solution to ensure that their understanding and assumptions about how V1C solution operates and interpretation of the data is accurate

Consider initial pilot evaluation to inform future evaluation plans Include a timeline for finalizing a long-term evaluation plan	The program evaluation plan can be more fully determined here to ensure enough time to design a thoughtful approach to and include early learnings from the first phase

GLOSSARY OF TERMS

These terms can be found throughout the Payor-V1C Contracting Toolkit. They are defined here to be understood in the context of these resources. Where available, citations of sites follow each definition in parenthesis.

Accreditation Association for Ambulatory Health Care (AAAHC). Ambulatory health care accreditation organization that accredits ambulatory surgery centers, office-based surgery facilities, endoscopy centers, student health centers, medical and dental group practices, community health centers, employer-based health clinics, retail clinics, and Indian/Tribal health centers, among others. (AAAHC website)

American Telemedicine Association (ATA). Established in 1993, ATA is a non-profit organization of 400 members committed to transforming health and care through enhanced, efficient delivery. (ATA website)

Affiliates. A corporation, partnership, joint venture, limited liability company, or similar organization other than a hospital that is devoted primarily to the provision, management, or support of health care services and that directly or indirectly controls, is controlled by, or is under common control of the hospital. For this definition, "control" means having at least an equal or a majority ownership or membership interest. (<u>Law Insider website</u>)

Application Programming Interface (API). APIs are mechanisms that enable two software components to communicate with each other using a set of definitions and protocols. (AWS website)

Assignment of Agreement or Obligations. An assignment of rights and obligations under a contract occurs when a party assigns their contractual rights to a third party. The benefit that the issuing party would have received from the contract is now assigned to the third party. (<u>Upcounsel website</u>)

Audit: A systematic assessment of performance within a healthcare organization. Audits typically examine financial, security, billing, and coding components to evaluate compliance with guidelines, agreements, and federal and state regulations.

Business Associate Agreement (BAA). A contract between a HIPAA-covered entity and an organization that is not a covered entity (the business associate) to ensure that the business associate will appropriately safeguard PHI by clarifying and limiting the permissible uses and disclosures of PHI by the business associate. (HHS.gov)

Covered Entity. See HIPAA Covered Entity.

Digital Medicine Society (DiMe). The Digital Medicine Society (DiMe) is the professional society for the digital medicine community to advance the safe, effective, equitable, and ethical use of digital medicine to optimize human health. (DiMe website)

Eligibility. Conditions must be met for an individual or group to be eligible for insurance coverage. (eHealth Insurance website)

The Federal Communications Commission (FCC). A federal agency responsible for implementing and enforcing America's communications laws and regulations. The FCC is an independent U.S. government agency overseen by Congress that regulates interstate and international communications by radio, television, wire, satellite, and cable in all 50 states, the District of Columbia, and U.S. territories. (FCC Website)

Fast Healthcare Interoperability Resources (FHIR) standards. A standard for describing data formats and elements and an application programming interface (API) for exchanging electronic health records. The Health Level Seven International Healthcare Standards organization created the standard to provide resources that can easily be assembled into working data systems that solve real-world clinical and administrative problems in healthcare. (HL7.org)

Federal Trade Commission (FTC). An independent agency of the United States government whose mission is to enforce civil U.S. antitrust law and promote consumer protection. The FTC shares jurisdiction over federal civil antitrust enforcement with the Department of Justice Antitrust Division. (FTC.gov)

Healthcare. Care, services, or supplies related to the health of an individual, including (i) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and (ii) sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription. (HHS.gov)

Healthcare Effectiveness Data and Information Set (HEDIS). A set of performance measures for health plans developed by the National Committee for Quality Assurance (NCQA) provides purchasers with information on the effectiveness of care, plan finances and costs, and other plan performance and quality measures. (NCQA website)

Health Insurance Portability and Accountability Act (HIPAA) Covered Entity. Health plans, health care clearinghouses, or health care providers that transmit health care information electronically as a part of a "covered transaction" defined in HIPAA, and therefore, must comply with rules and requirements set forth by HHS to protect the privacy and security of health information, and must provide individuals with certain rights with respect to their health information. (HHS.gov)

HITRUST. A security measure in healthcare is to ensure risk and compliance management frameworks, related assessment, and assurance methodologies in health technology. HITRUST Common Security Framework (CSF) is the leading information security framework for the healthcare industry. (<u>HITRUST website</u>)

Maintenance of Records/Duty of Care. Physicians have an ethical obligation to manage medical records appropriately, which includes the responsibility to safeguard the confidentiality of patients' personal information. This obligation encompasses not only managing the records of current patients but also retaining old records against possible future needs and providing copies or transferring records to a third party as requested by the patient or the patient's authorized representative when the physician leaves a practice, sells their practice, retires, or dies. (AMA website)

Management Services Organization (MSO). A healthcare-specific administrative and management entity that provides select core functions for a healthcare offering.

Management Group. See Management Services Organization (MSO).

Medical Group. See Professional Corporation (PC).

Member. See Plan Member.

National Committee for Quality Assurance (NCQA). A non-profit organization that works to improve healthcare quality by administrating evidence-based standards, measures, programs, and accreditation of health plans. (NCQA website)

Participant (or V1C participant). An individual who initiates participation in a healthcare offering. V1C participants are, therefore, individuals who initiate participation in a V1C solution.

Payor. The person, organization, or entity that sets service rates, collects payment, processes claims, and pays claims associated with healthcare services administered by a provider. This term most often refers to private insurance companies that provide their customers with health plans that offer cost coverage and reimbursements for medical treatment and care services.

Protected Health Information (PHI). Health and demographic information received by a Covered Entity that relates to the past, present, or future physical or mental health or condition of the identified individual, the provision of health care to that individual, or the payment for that health care. Protected Health Information is individually identifiable health information that HIPAA regulates. (HHS Website)

Plan Member. An individual who receives coverage of their healthcare expenses by a third-party payor.

Prior Authorization. Approval from a health plan may be required before a person gets a service or fills a prescription in order for the service or prescription to be paid for or covered by a health plan. (<u>HealthCare.gov</u>)

Professional Certification (or Professional License). Proof of training or capability in a specific area of expertise required for performing care duties. For example, a person who is a <u>Qualified Healthcare Professional</u> under the Social Security Act would have

to have the requisite licenses or certifications. Still, there may be appropriate professional licenses or certifications of other professionals.

Professional Corporation (PC) or Professional Association (PA): A type of corporate entity for which the shareholders must hold a professional license in the business they plan to operate. In many states, PCs are the only corporate entity allowed to engage in business to provide professional services. Certain states also limit ownership of a PC to licensed members of that profession. For example, a husband who does not hold a medical license cannot own shares in his spouse's medical practice.

Provider (or health care provider (HCP)). Under HIPAA, a provider of medical or health services and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. (HHS.gov)

Qualified or Eligible (plan member or V1C participant). An individual who, based on critical criteria, such as demographics, clinical information, or other factors, has the characteristics appropriate for receipt of a healthcare service. A qualified/eligible plan member is someone whose plan data suggests they are well suited for a given intervention (such as a V1C solution). A qualified/eligible V1C participant is a person who meets the medical and demographic criteria to be appropriate for a specific V1C solution.

Runout Period. The contractually agreed upon time frame during which a V1C solution may be obligated to continue to provide services after contract termination to ensure continuity of care.

Service Level Agreement (SLA). An agreement between an IT service provider and a customer. A service level agreement describes the IT service, documents service level targets, and specifies the responsibilities of the IT service provider and the customer. A single agreement may cover multiple IT services or multiple customers. (ITIL)

SOC Report. A System and Organization Control report that attests that a particular service is being provided securely. There are several kinds of SOC reports (e.g., SOC 1, SOC 2, etc). SOC 2 reports must apply to V1C solutions and address an organization's controls relevant to operations and compliance. SOC 2 includes availability, confidentiality, processing integrity, and privacy criteria and allows the flexibility to incorporate additional suitable criteria, such as adherence to public, industry-specific frameworks such as the HITRUST. SOC 2 Type reports align to progressing stages of compliance. A SOC 2 Type 1 report pertains to a service organization's system and the suitability of the design of controls, validating the design sufficiency of all administrative, technical, and logical controls. A SOC 2 Type 2 report expands on the Type 1 report to describe and evaluate at least six months of evidence of control effectiveness, attest to systems and controls in place and describe whether they function as defined by the service organization's management. (AICPA website)

Treatment, Payment, or Operations (TPO). Defined in the HIPAA Privacy Rule at 45 CFR 164.501, the circumstances under which covered entities are allowed to disclose patient information without needing authorization from patients. (HHS.gov)

Utilization Review Accreditation Commission (URAC). Leading nationwide quality accrediting organization for pharmacy, health plan, digital/telehealth, mental health, patient care management, and administrative management entities. (<u>URAC website</u>)

Virtual First Care (V1C). Medical care for individuals or a community is accessed through digital interactions where possible, guided by a clinician, and integrated into a person's everyday life. (V1C Coalition by DiMe website)

V1C service. V1C provider. V1C organization. See V1C solution.

V1C solution. A V1C approach that combines technology and human capital to enable the ability to initiate care anywhere at any time through telecommunication and digital technologies; intentional selection of the care setting matched to a person's clinical needs and preferences, with some aspects safely and effectively delivered virtually, and others necessitating in-person care; complete solutions that support a person to take all of the necessary steps in their health journey; and, adherence to all applicable laws that apply to HCPs, including best practices on standards of care, individual safety, security, privacy, and data rights. (V1C Coalition by DiMe website)