

## Acumen 2.0 Data Sharing Rules of the Road

Acumen 2.0 enables Acumen customers who license the software (“Practices”) to share a single Patient medical record (“Patient Record”) with each other, in order to provide a longitudinal perspective on the Patient’s medical history that is intended to improve the quality and efficiency in delivering health care.

The privacy, security and integrity of information contained in a Patient Record is a crucial component of the Acumen 2.0 community and Practices play a critical role in protecting the Patient Record from inappropriate access, use or disclosure. Accordingly, these Rules of the Road (including all appendices hereto, the “Rules”) establish the framework and requirements for how Practices will share a Patient Record, including circumstances under which Practices may access, use and disclose such information.

### Definitions

For purposes of these Rules, and unless specified otherwise below, the terms used in these Rules will generally have the meaning assigned to them under the Health Insurance Portability and Accessibility Act of 1996, as amended, and its implementation regulations (“HIPAA”).

**Acumen 2.0:** means the electronic health record and practice management software for nephrology practices, powered by EPIC, that Acumen makes available to the Practices.

**Authorization:** means a written request for access or authorization for the use or disclosure of Protected Health Information of a Patient that is compliant with HIPAA and applicable state law that is signed and dated by the Patient.

**Practice:** means any customer that has licensed Acumen 2.0 in accordance with a Master Service Agreement. For purposes of these Rules, Practice refers to the individual or entity listed in that Agreement. The Practice is responsible for ensuring that its workforce members (including the Practice’s medical, nursing and clerical staff), and all other users of Practice’s Acumen 2.0 license adhere to these Rules wherever applicable.

**Patient Record:** refers to the single patient medical record that is created for care and treatment purposes and contained within Acumen 2.0. The Patient Record includes information contained in each Practice’s Record Extract as defined more specifically below. The Patient Record does not include financial, billing, claims or reimbursement information pertaining to the Patient or the Practice, which is maintained separately within Acumen 2.0.

**Record Extract:** refers to the subset of the Patient Record that reflects a specific Practice’s treatment of the Patient. The Record Extract includes, for example, the Patient’s demographics, medications, diagnoses and allergies entered by any Practice for the treatment period, as well as encounter notes from the Practice who generated the Record Extract. The Record Extract does not include encounter notes from other Practices, claims / reimbursement information, or any other information that exists outside of the Patient Record. If only one Practice is ever associated with the Patient, then the Record Extract is

comprised of the entire Patient Record. If two or more Practices are associated with the Patient, then each Practice may generate a separate Record Extract reflecting its treatment of that Patient.

**Patient:** means the individual who receives health care from the Practice and is the subject of the Patient Record. The Patient's legally authorized personal representative, as defined by HIPAA and applicable state law, may exercise the rights of the Patient related to the Patient Record under HIPAA and applicable state law.

**Protected Health Information:** means any information that is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

**Sensitive Information:** means Protected Health Information that is subject to state or federal laws that exceed HIPAA requirements, including mental health treatment information, substance abuse treatment information that is subject to 42 C.F.R. Part 2, sexually transmitted disease or HIV/AIDs information or genetic information.

**Treatment Relationship:** means any relationship between an individual Patient and a Practice in which the Practice delivers or intends to deliver health care to the individual. Evidence of a Treatment Relationship includes scheduling or rescheduling an appointment for the Patient, even if the appointment has not yet occurred.

**Treatment:** means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination of management of health care by a health care provider with a third party; consultation between health care providers relating to a Patient; or the referral of a Patient for health care from one health care provider to another.

### **Access, Use or Disclosure of Patient Records for Treatment Purposes**

- 1) Practices may access, use and disclose a Patient Record for Treatment purposes only in accordance with federal and state laws applicable to that Practice. In all circumstances, Practices must comply with HIPAA when accessing, using or disclosing any information contained in a Patient Record.
- 2) Practices may create new Patient Records or access existing Patient Records subject to the limitations set forth in these Rules and as described below:

**New Patients:** A Practice may create a new Patient Record if (a) the Practice has a Treatment Relationship with the Patient, and (b) the Patient does not already have a Patient Record in Acumen 2.0.

**Existing Patients:** A Practice may access any existing Patient Record if it has an on-going Treatment Relationship with the Patient. *Examples include if a Patient initiates a Treatment Relationship with*

*a second Practice for the purpose of obtaining a second opinion or while temporarily residing in another state, or if the second Practice provides vacation coverage for the first Practice.*

Prior Patients: A Practice who previously had a Treatment Relationship with the Patient may continue to access the Patient Record after the Treatment Relationship has terminated, so that the Practice may generate a Record Extract reflecting its prior care and treatment. Due to technical system limitations it is not possible to remove a Practice from the Patient Record after the Treatment Relationship concludes, although the Practice's ability to use or disclose such information is limited by applicable federal and state law as well as these Rules. *An example would be if the Patient permanently transfers her care from the first Practice to the second Practice. Both Practices would have access to Record Extracts reflecting their own care and treatment of the patient. Although the first Practice would continue to have access to other information contained in the Patient Record, its ability to use or disclose such information for non-treatment purposes is limited according to these Rules.*

### **Access, Use or Disclosure of Patient Records for Non-Treatment Purposes**

- 3) A Practice may access, use or disclose information contained in its Record Extract for non-Treatment purposes to the extent permitted by HIPAA and other federal or state laws applicable to that Practice, subject to any limitations described in these Rules. For example, this includes using or disclosing information contained in the Record Extract for payment, health care operations, public health and research activities.
- 4) A Practice may only access, use, or disclose any information contained in the Patient Record but outside of its Record Extract for Payment or Health Care Operations purposes if (a) the Practice has obtained written consent from the Practice who has created such information in the Patient Record, and (b) for a Health Care Operations purpose, the Practice has, or has had, a Treatment relationship with the Patient.
- 5) A Practice may only access, use or disclose any information contained in a Patient Record but outside of its Record Extract for non-Treatment purposes unrelated to Payment or Health Care Operations if (a) the Practice has written Authorization from the Patient to access the Patient Record for that purpose, and (b) the Practice has obtained written Authorization from the Practice who has created such information in the Patient Record to use the information for that purpose.

### **Use or Disclosure of Deidentified Data**

- 6) A Practice may use or disclose any information contained in its Record Extract that is deidentified in accordance with the HIPAA Privacy Rule at 45 C.F.R. 164.514(b).
- 7) To the extent that a Practice has elected to participate in the CKD Data Registry offered by Acumen, as such services are described in the Master Services Agreement entered into by Acumen and Practice, Acumen will disclose deidentified information contained in the Practice's Record Extract.

### **Patient Consent or Authorization**

- 8) Each Practice is responsible for obtaining any Patient consent or authorization required by state and federal laws applicable to that Practice before accessing, using or disclosing information in a Patient Record. Each Practice is responsible for notifying Patients that they share a single Patient Record with other Acumen 2.0 customers in their notice of privacy practices or related documentation.
- 9) In particular, each Practice must ensure compliance with state and federal laws applicable to that Practice when accessing, entering, using or disclosing Sensitive Information in the Patient Record. Since it is not technically possible to segment or remove Sensitive Information contained within a Patient Record, Practices must not enter Sensitive Information in the Patient Record that cannot be shared with any other Practice (now or in the future) who is authorized to access the Patient Record for Treatment or non-Treatment purposes (such as quality improvement initiatives). If such Sensitive Information cannot be shared with all other Practices, such as if the Patient refuses to consent or “opts out,” such information must be maintained in a paper record or another electronic system maintained by the Practice.

#### **Revision or Amendment of the Patient Record**

- 10) Practices will verify the integrity and accuracy of information they contribute or amend in the Patient Record following generally accepted standards of medical practice. Each Practice associated with the Patient Record may amend or update the Patient’s list of active demographics, diagnoses, allergies and medications in order to ensure accuracy and up-to-date treatment information.
- 11) Practices will not rely solely on the Patient Record for information the Practice knows or, following generally accepted standards of medical practice, should know has potential for negative impact on Patient care. For example, Practices must verify documented allergies, current medications, relevant histories and problems with the Patient that appear inconsistent with the Practice’s own knowledge and experience.

#### **Removal of Individual Patient Records (“Opt-Outs”)**

- 12) Practices’ ability to access Patient Records for treatment and related purposes is critical to maintaining a continuity of Patient care and improving the quality and efficiency of health care, all for the benefit of the individual Patient. Accordingly, Practices must not restrict any other Practice from accessing, using or disclosing a Patient Record with the following exceptions:
  - a) The Patient does not consent or “opts out” of allowing other Practices to access, use or disclose the Patient Record, as described in these Rules;
  - b) Applicable law prohibits a Practice from sharing a Patient Record with other Practices; or
  - c) The Practice does not believe sharing the Patient Record with other Practices would be in the Patient’s best interests based on his or her professional judgment and the Practice temporarily “opts out” of sharing the Patient Record in order to verify the Patient’s preference (e.g., celebrity Patients).
- 13) The Practice may “opt out” of sharing the Patient Record with other Practices that are not already associated with the Patient Record. However, once a Patient Record is “opted out,” other Practices in the Acumen community cannot locate that Patient Record in order to schedule an appointment or provide treatment coverage for the Patient. Health care providers outside of the Acumen community – including

other providers within Epic -- also will not be permitted to access the Patient Record via Epic Care Everywhere or other interoperability connections.

- 14) However, Practices may create a duplicate Patient Record that does not automatically pull data from Epic CareEverywhere or other interoperability connections. Those Practices manually may pull CareEverywhere data into the Patient Record and/or share their Record Extract with other Practices or health care providers for treatment purposes by mail, fax or e-mail.
- 15) Given the implications on continuity of care, it is imperative that the Practice provide the Patient with sufficient information about the risks of “opting out” of sharing the Patient Record, so the Patient may make an informed decision that meets his or her treatment needs.

### **Security and Access Control Measures**

- 16) In accordance with HIPAA, Practices must implement reasonable safeguards to ensure the privacy, security and integrity of all information contained in Patient Records. This includes implementing security and access control measures that meet the minimum standards required by HIPAA as well as any other federal or state laws applicable to the Practice.
- 17) At a minimum, this requires Practices to:
  - a) Train all of the Practice’s workforce members (i.e., end users granted access by Practice) regarding the appropriate and inappropriate use of Acumen 2.0 generally and Patient Records specifically;
  - b) Assign unique individual logins and strong passwords for each workforce member to access Acumen 2.0, with no shared or public logins or passwords at any time;
  - c) Develop procedures for access to Patient Records in emergency situations for appropriate Practices;
  - d) Use and regularly monitor the audit capabilities of Acumen 2.0;
  - e) Require all information contained in Patient Records to be treated with the same privacy and security standards as any of other clinical documentation/Patient Protected Health Information maintained by the Practice; and  
Appoint one workforce member as the Practice’s Acumen 2.0 Coordinator who will act as the liaison with all other Practices and with Acumen, and whose responsibilities include timely communication and deployment of information within the organization.
- 18) Acumen 2.0 includes certain privacy and security settings, such as end user access controls and restricted department settings, that Practices must review and configure based on their unique workflows and implementation. Practices must implement security and access measures with respect to the communication infrastructure of Acumen 2.0, including access to the communication servers and the digital certificates used to validate Practice as an Acumen 2.0 Practice, that meet the minimum standards required by HIPAA and the law applicable to the Practice.
- 19) Practices must implement disciplinary procedures with respect to their workforce members’ inappropriate use of Patient Records in the same manner as the Practice would do for inappropriate use of similar Patient or confidential information.

20) If a security vulnerability is identified that poses an immediate threat to the confidentiality, integrity, or availability of Patient Records, then Acumen may take immediate action, in its reasonable discretion, to limit or suspend access to Patient Records by Practices affected by such vulnerability. Any such action will be designed to both (i) mitigate the risk to the confidentiality, integrity, and availability of Patient data due to the security vulnerability, and (ii) permit as much Patient data sharing as possible for treatment purposes to continue occurring while such action is in effect.

### **Audits and Inquiries**

- 21) Acumen 2.0 creates a community of Practices, all with the same goal of improving Patient care through access to Patient Records for appropriate purposes in accordance with applicable law and standards of care. It is critical that all Practices cooperate with each other regarding issues that may arise and work together to informally resolve issues regarding Patient Records.
- 22) Practices are responsible for monitoring the Audit Logs of all individual users and other Practices who access Patient Records that they are associated with, in order to determine that such access was appropriate in accordance with these Rules. In particular, Practices monitor access by generating a "Access Report" on demand or at designated intervals selected by the Practice. Practices also may generate an "Audit Trail Report" to review certain patient information that has been updated or changed in the Patient Record. Practices also may consult Acumen staff for requests related to other types of reports.
- 23) If Practices have any question or concern about access, use or disclosure of information contained in a Patient Record, then Practices must communicate directly with each other and attempt to resolve any disputes in good faith and a manner consistent with their applicable law, standards of practice and Patient choice.
- 24) In particular, Practices must comply with any valid Patient request for access to medical records or HIPAA Authorization that is signed by a Patient or the Patient's legally authorized personal representative and comports with federal and state law. Practices cannot refuse to allow another Practice to access, use or disclose the Patient Record in a manner that is consistent with a Patient's or a Patient's legally authorized personal representative's valid written Authorization.
- 25) Practices must fully cooperate with each other in this process, including providing detailed information to each other as to what information was accessed or needs to be accessed from the Patient Record, by whom and for what purpose. Practices must provide the requested information (including copies of any Patient request for access or Authorization forms collected at the point of care) within five (5) business days unless mutually agreed.
- 26) If Practices are not able to resolve any question or concern directly with each other, they may direct a grievance to the Governing Council Dispute Resolution Committee as described below.

**Governing Council and Dispute Resolution Committee**

- 27) Acumen is a technology vendor and services provider. As such, its role is not to act as a policing authority for disputes within the Acumen 2.0 community. Instead, a governing council of elected representatives will adjudicate disputes between Practices related to these Rules of the Road (the “Governing Council”).
- 28) The Governing Council members shall perform their duties in good faith and with a view to the overall interests of the Acumen 2.0 community, with that degree of diligence, care, and skill that ordinarily prudent persons would exercise under similar circumstances in like positions.
- 29) The Governing Council shall be comprised of three (3) voting members that are members of and selected by the Acumen Medical Advisory Board (“MAB”) according to the following process:
- a) Each Governing Council member shall serve a term of one (1) year.
  - b) Members are not paid for participation on the Governing Council.
  - c) When a Governing Council position is vacant or expiring within 90 days, the Recorder of the Governing Council will publish a call for nominations to all MAB members. Each MAB member may nominate only one candidate and provide relevant biographical or professional information. To be considered for election, a candidate must be a current Acumen MAB member with a membership term coinciding or exceeding the one-year term of the Governing Council.
  - d) The Recorder shall set dates for the opening and close of voting to ensure MAB Members have at least five (5) days to submit their vote, while also ensuring at least fifteen (15) calendar days prior to the end of the term for Governing Council Members being replaced by the voting process. The Recorder may provide additional time if the number of nominees are less than the number of positions to be filled.
  - e) The specific votes of each MAB member shall be kept confidential by the Recorder, who will report only the total number of votes for each candidate. If there is a tie impacting the outcome, a runoff vote, with one (1) vote per MAB member, for each affected seat will be held over the five (5) Days immediately following the date the results are reported, with the results of the runoff reported to all members by the Recorder.
- 30) The Governing Council also will be comprised of two (2) members appointed by Acumen Physician Solutions from among its employees or officers. These members are entitled to participate in any proceedings and deliberations of the Governing Council but will not have a vote on the Governing Council unless otherwise specified in these Rules.
- 31) The Governing Council members shall select one member to serve as the Chair. The Chair’s duties include convening and facilitating meetings of the Council, organizing the formation of any Grievance Committees, and organizing the formation of any other committees the Governing Council decides are necessary.
- 32) The Governing Council members shall select one member to serve as the Recorder. The Recorder’s duties include administering the nomination and election of Governing Council members as described in these Rules and maintaining records of all elections and actions of the Governing Council, including meeting minutes.
- 33) All discussions and records of the actions of the Governing Councils and Panels will be confidential and will be disclosed only to Participants, Governing Council Members, and Acumen Physician Solutions.

- 34) Any elected Governing Council members shall be removed by affirmative vote of two-thirds (2/3) of all MAB members.
- 35) The Governing Council will have no authority to determine compliance with the Acumen 2.0 Master Service Agreement or any other agreements related to the Participants, allocate liability associated with violation of the Rules of the Road, or assess any monetary penalty or damages of any kind.

**Grievance Resolution Procedure**

- 36) In the event that any Practice is unable to resolve a dispute with another Practice involving a Patient Record and believes another Practice's conduct violates the privacy, security or integrity of the Patient Record, then the Practice may submit a grievance to the Governing Council.
- 37) In addition, during the pendency of the grievance process and notwithstanding anything contained in these Rules, if a Practice reasonably determines that the threat to privacy, security or integrity of the Patient Record still exists based on the alleged violation of the Rules of the Road, then the Practice may temporary "opt out" the Patient Record subject to the limitations in these Rules.
- 38) Each Practice named in a grievance must agree to cooperate with any investigation conducted by the Governing Council, as well as any decision rendered by the Governing Council.
- 39) The Governing Council shall render a decision that is reasonably tailored to ensure compliance with these Rules, health care providers' access to Patient information for legitimate Treatment purposes, and the privacy, security and integrity of information contained in the Patient Record. Depending on the circumstances and technical feasibility, the Governing Council may conclude no action is warranted, issue a warning to any Practice and individual end user regarding their obligations under these Rules, require a Practice or individual end user to undergo additional workforce training, or temporarily or permanently remove a Practice or individual end user from Acumen 2.0. In addition, Practices must agree to permit Acumen to modify the Acumen 2.0 related-configuration in its system to the extent necessary to carry out the decision of the Governing Council. The decision of the Governing Council is final and binding on the Practices involved in the disputes and is not subject to judicial review.
- 40) Practices agree not to sue any individual member of the Governing Council, Acumen, its officers, employees, contractors, or agents with respect to any action taken by Governing Council or Acumen related to the resolution of any grievance. This includes, without limitation, Acumen removing any Practice from the Acumen 2.0 community in accordance with these Rules, as well as any harm to a Patient because Practices did not have access to the Patient's Patient Record as a result of Acumen's action or inaction. Nothing in these Rules of the Road limits any rights of a Practice to seek indemnification from another Practice pursuant to the terms of the Master Service Agreement.

**Inappropriate Use Or Disclosure, Security Incidents and Data Breaches Involving Patient Records**



- 41) Acumen will, to the extent known by Acumen, report inappropriate use or disclosure of information contained in Patient Records to affected Practices in accordance with the federal and state laws and contractual obligations applicable to Acumen.
- 42) If a Practice separately becomes aware of inappropriate use or disclosure of another Practice's information contained in Patient Records, it must notify the affected Practice(s) in accordance with these Rules without undue delay and in no less than ten (10) days of the date from when the Practice knew of the inappropriate use or disclosure.
- 43) Each Practice must ensure compliance with federal and state laws applicable to that Practice with respect to its inappropriate use or disclosure of any Patient Record, as well as inappropriate use or disclosure of information contained in its Record Extract. In particular, each Practice must assess whether such unauthorized use or disclosure constitutes a privacy or security breach under HIPAA and applicable state law. Each Practice also must notify affected individuals and regulatory agencies in accordance with the Practice's applicable law, which may vary from Practice to Practice.

#### **Removal of Patient Information from Acumen 2.0**

- 44) Information entered in a Patient Record may not be removed or deleted due to technical limitations.
- 45) If a Practice terminates the Master Service Agreement between Practice and Acumen, Acumen will facilitate the transfer or migration of that Practice's Record Extracts in accordance with the terms of the applicable Master Service Agreement.
- 46) Acumen will not purge a Patient Record from the Acumen 2.0 community unless it is technically feasible to do so and to the extent permitted by its contractual commitments to any affected Practices.

#### **Amendments to Rules of the Road**

- 47) These Rules of the Road are expected to be continually refined in order to meet the needs of Acumen and the Practice community or to ensure compliance with laws, regulations and standards of care applicable to all Practices. Accordingly, changes to the Rules may be made by Acumen or the Governing Council from time to time in accordance with this section. Practices also may submit proposed amendments to Acumen or the Governing Council for their consideration.
- 48) The Governing Council may, by majority vote, propose amendments to these Rules of the Road. Such amendments will be effective if agreed by a majority of Acumen MAB Members and if Acumen ratifies the amendment. Acumen, or the Governing Council, will inform each Practice's Acumen 2.0 Coordinator of the results of the vote, and each Acumen 2.0 Coordinator will communicate the result and effect of the vote within the coordinator's organization.
- 49) In addition, these Rules of the Road may be amended by Acumen, in its reasonable discretion, in the following circumstances:

- a) when necessary to ensure the privacy, security or integrity of information contained in Acumen 2.0 generally or Patient Records specifically;
  - b) if necessary due to the Acumen system architecture;
  - c) to conform to state or federal laws or regulations applicable to Acumen and/or one (1) or more Practices; or
  - d) to conform to Acumen's obligation to adhere to Epic Community Connect Accreditation requirements.
- 50) The amended Rules will be posted on Acumen's user web site and generally will be effective forty-five (45) days after the date of posting. However, a change or amendment may be implemented immediately or in less than 45 days if the change or amendment is intended to address an issue of immediate concern in Acumen's reasonable discretion.