

Mobile Health SaaS Platform for Patient Education, Engagement and Informed Consent



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CEOCFO: Dr. Fialkov, what is the concept behind Rational Surgical Solutions, Inc and Rati-F®?

Dr. Fialkov: Rational Surgical Solutions is essentially the holding company. Our flagship product and subsidiary company of RSS is Rati-Fi®. Rati-Fi is a product for patient education and engagement and coordination of their care that has, at the core of it, the concept of informed consent and a standardized method of delivering that service.

CEOCFO: Would you explain the problem and how you are able to make a difference?

Dr. Fialkov: Informed consent is a process which is legally mandated before any patient is to undergo a procedure or a treatment which carries risk. The current standard for delivering informed consent is a discussion with the physician and then a signature on an informed consent document (an actual piece of paper.) The standard process leaves lots of room for improvement. First of all, from a documentation standpoint, if there is any dispute about what treatment or procedure the patient actually agreed to and what information was communicated to them comes up them, it really becomes a he said/she said type of situation. Also, the concept of informed consent is really dependent on the patient truly understanding what is going to happen, being given different options and having time to think about their choices before making them. In reality, due to mounting time pressures as a result of a worsening workforce shortage, individual physicians, healthcare teams, and hospitals do not have the luxury of spending the amount of time with the patient and their family to do the process justice. Inadequate informed consent can lead to poor outcomes. It can lead to increased costs for the system. It ultimately can lead to lawsuits for the healthcare team. Of course, most importantly, patients and families may not know what to expect, may have unrealistic expectations and may not be properly prepared to take care of themselves before and after surgery.

CEOCFO: What have you developed?

Dr. Fialkov: We have developed a system called Rati-Fi. Rati-Fi is software as a service. It is a multi-component system which consists of an iPad application as well as a web application. Through the system patients can be educated. They have access to resources in the form of high quality video content in multiple languages. The Rati-Fi process includes recording the consultation between the physician and the patient and this is all auditable, trackable and shareable by the patient with their family members and care givers.



CEOCFO: *What level of procedure are we talking about that needs consent? Is it something like a colonoscopy or more serious situations?*

Dr. Fialkov: Anyone undergoing a procedure that has significant material risk should go through an informed consent process first. There are low risk procedures like having your blood drawn and for those typically just a verbal consent is satisfactory. However, if someone is even going for a screening colonoscopy, technically they should undergo full consent, and understand the risks of that procedure and the benefits and the alternatives to doing it. Maybe there is not a great alternative, but at least they need to be given all of that information before they proceed. Most importantly, they need to understand that there is preparation involved. Case in point, there is a high rate of cancellations at endoscopy centers and outpatient surgery centers and even for major surgery in the hospital setting, because many patients are not properly prepared, because they did not understand everything that was involved in the procedure. There is a potentially enormous loss of revenue for a hospital or a surgery center because of that. Furthermore, there is potential harm to the patient because of delay in care, and sometimes patients may decide not to followup with their rescheduled procedure.

CEOCFO: *Are patients looking for a better way, in addition to the medical community or do patients, at large, need to understand they should want a better way and that they should focus more on what they are signing; what they are agreeing to?*

Dr. Fialkov: The answer is both. I am a urologist by training, and this is a product that came out of my own experience over 14 years of practice as well as listening to patients and their families. There are a few individuals who are passive in receiving care, but there is a growing emphasis, even pressure, from patients and patient advocacy groups for better education, better counseling and more active involvement in their own decision making when it comes to healthcare.

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CEOCFO: *How would a doctor or hospital use Rati-Fi?*

Dr. Fialkov: First, the individual or organization opens an account with Rati-Fi. Once the account has been activated for the number of “seats” requested, the system is accessed through a cloud-based web application. Whenever a patient is registered for a visit or is scheduled to undergo a procedure or surgery, a link to that patient’s Rati-Fi account is created and updated automatically. The patient then has access to all of their educational materials specific to that institution, specific to them and even specific to the individual caregiver in that institution. Therefore, it is all customized to them, configurable for them and that may include anything from educational videos to video documentation of their encounter with their doctor, preoperative and postoperative text-based instructions, maps; any of the information that the hospital or institution would want to share with the patient. The patient is encouraged to login and review their information. We are able to track what they review. Therefore, a care coordinator at the hospital or a nurse or a practice manager can actually look at our dashboard and say, “I have ten patients scheduled for a colonoscopy at our endoscopy center next Monday and only half of those patients have actually reviewed the instructions. I better get in touch with them to reschedule or to either remind them that they need to complete these preparations or we cannot do the procedure or we need to reschedule or maybe we even need to double book that, because there is a high likelihood of given this patient’s previous behavior they are not going to show up.” Once at the doctor’s office, outpatient surgery center, or hospital, the consent is “finalized” using an iPad application. The signed and date and time-stamped document is sent to the patient’s chart in the EHR where it is archived. All other documentation is stored securely in the Rati-Fi database.

CEOCFO: *You typically sign a consent form at the time you are scheduling. Would that not happen anymore with your system? Would it be after there has been some review?*

Dr. Fialkov: Yes, it does change. Rather than the patient receiving a folder of instructions in the mail which they may or may not read and follow and signing a piece of paper immediately before a procedure, they will enjoy a coordinated care episode with a comprehensive educational and preparatory process customized for that patient and their support network. They will access to their healthcare team through an elegant and intuitive interface. This is in juxtaposition to the standard process done by the vast majority of healthcare organizations which does not meet federal requirements and results in significant lost revenue.

CEOCFO: *Have there been ways that have been tried in the realm that you are doing or is this a new concept that there can be this digital component that makes sense?*

Dr. Fialkov: This truly is a novel product that standardizes the entire informed consent process, follows federal guidelines and best practices and then goes one step further. Up until recently, the technology was not available to do what Rati-Fi

does! Now, using the cloud and using mobile devices with video cameras, we are able to do something which doctors, risk managers, and patients dreamed of, but were not actually able to execute.

CEOCFO: *Is the information available to the patient coming from the doctor or the institution or do you have some input into how or what they should present?*

Dr. Fialkov: We offer high quality video content, because that was actually a request from nearly all of the institutions with which we have engaged. We have very strict quality requirements and have established a partnership with an experienced medical video education company to provide the content doctors, hospitals, and patients and their families have demanded. We also provide, as part of the licensing agreement, training for the staff about how to properly communicate on camera, what the components are for true informed consent based on federal government requirements and best practices. We help them with that, but there is a lot of configuration and customization which our platform allows for the individual institution including the capability of utilizing videos the organization has produced themselves.

CEOCFO: *How are you able to present all of the possibilities of what could happen without frightening people?*

Dr. Fialkov: That is a great question! First of all, patients and their families are hungry for information about their medical conditions and especially any upcoming interventions. You can actually go to our website, <https://rati-fi.com>, which has the appropriate references. The studies we cite have determined that giving people a high-level view of what is going to be happening to them decreases anxiety. Our video content provider comes from a motion picture background. In fact, he is an NYU educated film producer. The way we have approached educating patients is to tell a story while simultaneously taking the patient through a step-by-step educational process. The real key is making it like a motion picture, a little six to ten minute motion picture explaining, "This is you, this is what is going on, this is what is going to happen and yes there are risks and this is what they can look like." We have made a concerted effort to NOT take the FDA-mandated approach that pharmaceutical commercials use, bombarding the patient with thousands of potential problems. We do list the most likely complications or poor outcomes which can result from the surgery. Then we cover our bases by saying, "There are other things which can go wrong in this procedure, but they are much less likely. Overall the procedure is successful." Feedback from the patients and families that use Rati-Fi confirm that our approach helps decrease anxiety (rather than increase it.)

CEOCFO: *Where are you today? Are people using what you have created or are you still in development?*

Dr. Fialkov: We have a product that is market ready. We have clients and our trajectory is increasing rapidly. We are really gaining traction and we anticipate some press releases in the next few weeks, announcing our implementation in large institutions in large metropolitan areas. That is about as I will go with that, but we do have users and people have seen great benefit from Rati-Fi

CEOCFO: *Are you seeking funding or partnerships as you move forward?*

Dr. Fialkov: We will be seeking funding going forward to propel our growth. However, right now we are in good shape from that standpoint. We are working towards partnerships with a number of different organizations in different spaces, but all touching healthcare. For example, healthcare consulting firms, medical malpractice carriers, medical equipment, leasing companies and distributors document and infrastructure companies and group purchasing organizations. We are actively interviewing a number of potential partners in each space to see who would be the best fit for us.

CEOCFO: *What surprised you throughout the process of concept and development and now being really close to usage?*

Dr. Fialkov: That is a good question. Even coming from inside the space as a physician, the biggest surprise was the degree of turmoil our healthcare system is in at this point in time as a result of the abortive attempt to repeal the ACA. This has definitely impacted purchasing decisions by many of our customers.

