

InfuSystem Holdings, Inc
Form 8-K
June 02, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 2, 2016

InfuSystem Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of
incorporation or
organization)

001-35020
(Commission
File Number)

20-3341405
(I.R.S. Employer
Identification No.)

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31700 Research Park Drive

Madison Heights, Michigan 48071

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (248) 291-1210

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

InfuSystem Holdings, Inc. (the Company) is filing this Current Report on Form 8-K to provide an update to investors regarding a policy change recently announced by the Centers for Medicare and Medicaid Services (CMS).

On April 25, 2016, CMS issued a policy clarification article in the form of Medical Learning Network Matters® Number SE1609 Medicare Policy Clarified for Prolonged Drug and Biological Infusions Started Incident to a Physician's Service Using an External Pump (SE1609). The Company previously disclosed the issuance of SE1609 in Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations and updated Item 1A. Risk Factors in its most recent Quarterly Report on Form 10-Q for the first quarter of 2016 filed on May 10, 2016.

In its prior disclosure, the Company indicated that its management was in the process of assessing the potential impact of SE1609 on the Company's business. The Company, with input from its regulatory advisors, has completed its initial assessment. Based on this assessment, the Company interprets SE1609 as no longer permitting Durable Medical Equipment (DME) suppliers to submit billings to the DME Medical Administrative Contractors (MACs) for the infusion pumps and supplies provided to Medicare patients in the circumstances described in SE1609, which is a sudden shift from prior CMS policy and practices. More particularly, SE1609 provides that when a drug is provided incident to physicians' services rendered to patients while in the physician's office or hospital outpatient department, the external pump is not separately billable as DME. This applies to not just the Company, but any DME supplier, home infusion company, hospital outpatient clinic or physician office that provides ambulatory infusion pumps in a setting where treatment is initiated in the infusion setting prior to the patient being sent home for long term infusion. SE1609 states that an ambulatory infusion pump and supplies are not separately reimbursable as DME when a Medicare patient leaves an infusion setting and goes home with a pump. SE1609 indicates that the administration of the drug billed to the local Medicare Contractor should also include payment for the DME used in furnishing the service. Under existing laws, in order for Medicare to cover the cost of the drug and external pump, a physician, hospital, clinic, home infusion therapy company or DME supplier must incur a cost for the drug and pump.

The Company has historically submitted billings directly to DME MACs for its infusion pumps and portfolio of related services in the circumstances described above. In this regard, Medicare accounted for 20% and 19% of the Company's total revenues for the three month period ended March 31, 2016 and fiscal year ended December 31, 2015, respectively, and 15% and 20% of Company's consolidated accounts receivable, net as of March 31, 2016 and as of December 31, 2015, respectively. As a result of SE1609, the Company will now submit these billings directly to physicians or hospitals who, in turn, will seek reimbursement from Medicare. In these cases, the providing physicians or hospitals, rather than Medicare, will be the primary obligor to the Company for payments for the Company's infusion pumps and portfolio of related services.

It is important to note that SE1609 applies only to Medicare patients and, therefore, the Company currently expects that SE1609 will have no direct material impact on the majority of patients of the Company's customers who are insured by private commercial carriers. In these cases, which currently represent a substantial majority of the Company's revenues, the Company already submits billings directly to these private commercial carriers.

While the Company intends to continue to advocate for the safety, efficiency and continuity of care for Medicare patients using its services as a result of SE1609, the Company has elected for an interim period, pending further CMS guidance, to (i) hold and not submit current billings to Medicare, for treatments post May 10, 2016, and (ii) institute a fully compliant temporary alternative billing arrangement to its oncology clinic customers for Medicare patients. The alternative billing arrangement will be designed to preserve existing relationships with these customers and be a single source for the home infusion treatment for all patients, including Medicare.

The Company estimates that the transition to the temporary alternative billing arrangement and other recent announcements regarding commercial billing will have a net reduction to its operating income (loss of net revenue net of associated expenses saved) of approximately \$1 million annually. Furthermore, there can be no assurances that SE1609 will not further impact future revenues and net income as a result of the prevention of the Company from submitting billings which the Company is now holding or implications from other risks referred to in the Risk Factors section of the Company's Annual Report on Form 10-K for 2015. In addition, the Company's current interpretation of SE1609 is subject to change depending upon future CMS guidance or interpretations or other regulatory developments.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements regarding the Company's interpretation of SE1609, the anticipated impact of SE1609 on the Company's business and financial results and the anticipated impact of the Company's proposed alternative billing arrangement constitute forward-looking statements. These statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially from the forward-looking statements, including those described above. You should not rely on any forward-looking statement as a prediction or guarantee about the future. These forward-looking statements speak only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INFUSYSTEM HOLDINGS, INC.

By: /s/ Eric K. Steen

Eric K. Steen

President and Chief Executive Officer

Dated: June 2, 2016