REPORT 7 OF THE COUNCIL ON MEDICAL SERVICE (A-17)
Retail Health Clinics
(Resolution 705-A-16)
(Reference Committee G)

EXECUTIVE SUMMARY

At the 2016 Annual Meeting, the House of Delegates referred Resolution 705, "Retail Health Clinics," sponsored by the Washington Delegation. Resolution 705-A-16 asked the American Medical Association (AMA) to study retail health clinics, with consideration of patient care delivery to ensure patient safety, the appropriate level of oversight as entities separate from an independent physician's practice and other health care facilities, and potential conflicts of interest where such clinics are located within a store that includes a pharmacy as such co-locations could result in incentives to provide costly, unnecessary, inappropriate, and uncoordinated health related services. The resolution also asked the AMA to consider the merits of pursuing legislation to ensure appropriate oversight.

In this report, the Council notes that retail health clinics have been playing a steadily increasing role in the health care marketplace since they first opened in 2000. Convenience, accessibility, and clear pricing seem to be the largest drivers of their growth. Nonetheless, the Council acknowledges and agrees with concerns that the retail clinic model may have the effect of fragmenting care delivery by potentially undermining the medical home and the patient-physician relationship. When considering the appropriate role of retail clinics, the Council believes that the patient's best interest is of paramount concern.

The Council believes that, with the appropriate safeguards and guidelines, retail clinics have a place in the delivery of health care and that they may serve as a complement to, rather than a substitute for, the primary care physician or usual source of care. The Council recommends the adoption of additional safeguards and guidelines to encourage value in retail health clinics consistent with current AMA policy on store-based health clinics.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 7-A-17

Subject: Retail Health Clinics

(Resolution 705-A-16)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee G

(J. Clay Hayes, MD, Chair)

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At the American Medical Association's (AMA) 2016 Annual Meeting, the House of Delegates referred Resolution 705, "Retail Health Clinics," submitted by the Washington Delegation. The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2017 Annual Meeting. Resolution 705-A-16 asked:

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That our AMA study retail health clinics, with consideration of patient care delivery to ensure patient safety, the appropriate level of oversight as entities separate from an independent physician's practice and other health care facilities, and potential conflicts of interest where such clinics are located within a store that includes a pharmacy as such colocations could result in incentives to provide costly, unnecessary, inappropriate, and uncoordinated health related services. The resolution also asks the AMA to consider the merits of pursuing legislation to ensure appropriate oversight.

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This report provides an overview of retail health clinics, notes the various retail clinic models in operation, the clinics' extent of physician oversight, explores continuity of care and patient safety, unnecessary or inappropriate care and potential cost savings, outlines the financial impacts of retail clinics, summarizes conflicts of interest and legislative activity pertinent to retail clinics, outlines relevant policy, and proposes new recommendations that build off the current body of policy on store-based clinics.

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BACKGROUND

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Retail health clinics have been playing a steadily growing role in health care. The first retail clinics opened in 2000. By 2010, there were estimated to be about 1,200 retail clinics in operation, and the most recent estimates predict that there will be more than 2,800 clinics this year. The most important drivers of this growth include convenience, after-hours accessibility, and clear pricing at the point of care.

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- It is important to note that commercial clinics fall into two main categories: urgent care and retail.
- 30 The Council limited the scope of this report to retail health clinics as directed by referred
- 31 Resolution 705-A-16. Retail clinics typically provide basic primary care treatment, screening, and
- 32 diagnostic services. They focus on providing convenient care for a limited number of acute
- conditions such as colds, sore throats, and ear infections. In most instances, retail clinics are
- 34 staffed by nurse practitioners and physician assistants. However, in some states, nurses work under

the remote supervision of a physician.³ In all states except Michigan, physician assistants work under physician supervision; Michigan requires a collaborative arrangement.

Generally, retail clinics follow one of three business models. In the first, the clinic is owned and operated by the parent store that houses it. In the second, the clinic is owned by an independent company that partners with a retail store to house the clinic. In the third model, the clinic is owned by a hospital, a physician group, or another health care provider. Nearly three quarters of clinics follow the first model.⁴

Retail clinic use is heaviest among young adults, minority families, and families with children.⁵ Retail clinic users are generally younger than patients seen in primary care offices and emergency departments.⁶ Only 39 percent of retail clinic users report having an established relationship with a primary care physician, which contrasts to about 80 percent of the general population reporting such a relationship.⁷

Retail clinics have established a niche in the health care system based on their convenience and high levels of patient satisfaction. Convenience is the reason most overwhelmingly cited for visiting a clinic. Retail clinics generally have weekend or evening hours and no need for appointments. The recent proliferation of retail clinics provides many consumers with an alternative source of care for a limited number of routine services at the consumer's convenience. Despite the effort in many physician practices to expand hours, consumers continue to seek care in the retail setting due to perceived preferential wait time and overall convenience.

 Nearly all retail clinics accept some form of private health insurance and many accept public health insurance options. Sixty percent of small firms and 73 percent of large firms cover services offering health benefits provided in retail clinics in their largest health plan. Some plans even encourage enrollees to visit retail clinics through reduced or waived copayments, which is a practice AMA policy condemns (H-160.921).

 Despite the finding that retail clinic use is more likely among minority families and that retail clinic users are disproportionately likely to live in poorer neighborhoods, thus far, the number of retail clinics that target underserved populations is limited. Retail clinics have not taken up the role of providing care in medically underserved areas and are unevenly distributed across neighborhoods. Specifically, retail clinics are often placed in higher-income, urban and suburban settings with higher concentrations of white residents and fewer black and Hispanic residents and fewer residents living in poverty. Medicaid payment rates present an obstacle to opening clinics in low-income neighborhoods, and managed care beneficiaries may need to pay out of pocket for care at retail clinics. Accordingly, retail clinics do not seem to be a component of the solution to primary care shortages and access to care disparities in underserved communities.

Retail clinics pose both challenges and opportunities for policymakers and regulators. Supporters of the model point out that retail clinics serve as a lower-cost alternative to emergency departments or physician offices when patients have minor ailments. Others worry that retail clinics serve only as a way to fragment care. Concerns include lack of physician oversight potentially undermining quality of care and disrupting continuity of care and the physician-patient relationship, thereby potentially weakening the medical home. In particular, there are concerns with patient safety and the worry that individuals may try using a retail clinic when they have a problem beyond the scope of the retail clinic's limited services or expertise.

PHYSICIAN OVERSIGHT

 Although some retail clinics are staffed by physicians, most are staffed by nurse practitioners and physician assistants. ¹⁰ Retail clinic operators claim that these arrangements help sustain their economic viability. ¹¹ Direct licensing of health care facilities and providers gives states the ability to monitor and enhance patient safety, so state practices and laws vary on the flexibility of non-physician medical professionals to prescribe drugs and practice. ¹² As previously stated, some states allow nurse practitioners to provide care independent of physician involvement while most states require physician supervision and still others mandate collaboration. Again, all states except Michigan require physician assistants to be supervised by physicians and Michigan requires a collaborative arrangement.

CONTINUITY OF CARE AND PATIENT SAFETY

Particularly for patients with a medical home, there is concern that retail clinics do not communicate with primary care providers about services delivered, thereby potentially undermining the physician-patient relationship or medical home. Moreover, patients rarely receive follow-up care after a visit to a retail clinic, and often, after a patient receives care in a retail clinic, there is no follow-up communication with a patient's primary care provider or usual source of care, exacerbating the concern that retail clinics may fragment care.

Additionally, there is increasing concern with retail clinics expanding their scope to include the screening and treatment of chronic diseases such as asthma and hypertension. Many believe there is a need to distinguish between screening and monitoring disease versus the active management of chronic disease, potentially raising liability concerns.

UNNECESSARY OR INAPPROPRIATE CARE AND COST SAVINGS

Several studies have examined the cost of retail clinic services and compared them with other health care settings. The results show that retail clinics typically offer lower per-episode costs than urgent care centers, emergency departments, and primary care providers. Therefore, retail clinics may reduce overall health spending if patients substitute care at retail clinics for care at more expensive sites of service. However, retail clinics may also increase overall utilization by attracting patients who might not have otherwise sought care, thereby increasing overall health spending.

Recent studies challenge the idea that convenience settings like retail health clinics substitute for emergency department (ED) visits. It is estimated that up to 20 percent of ED visits are for low-acuity conditions, and it is possible to treat many ED patients for low-acuity conditions in low-cost settings such as retail clinics. However, retail clinics to date have not been associated with a meaningful reduction in low-acuity ED visits. Accordingly, it seems that instead of lower costs associated with ED visits, retail clinics may be substituting for care in other settings, such as primary care practices, or they may be increasing utilization by prompting patients to seek care for minor conditions that patients otherwise would have treated at home. One recent study found that 58 percent of retail clinic encounters were for care that a patient would not have otherwise sought, and not in lieu of care from an outpatient provider like a primary care physician. This new utilization is associated with a modest increase in health care spending of \$14 per person per year. Overall, it seems the predominant effect of retail clinics is "new use," meaning patient visits to these settings are mostly additive rather than substitutive.

Retail clinics create new use for a number of reasons: they meet unmet demands for care, the motivations for seeking care differ in retail clinics versus EDs, and groups of people are more

likely to use EDs for low-acuity conditions because they have little access to other types of care. Additionally, in some communities, the demand for episodic acute care exceeds the supply of physicians or facilities, and this desire for care is met conveniently by settings such as retail clinics. Retail clinics meet consumer expectations by delivering the desired service, with minimal time investment (e.g., travel, waiting).

FINANCIAL IMPLICATIONS

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In economic terms, the increased use of health care services created by retail clinics can be termed "supply-sensitive care," in which the supply of a specific resource and not necessarily the demand for the resource influences utilization. ¹⁸ People select the setting they think can best care for them. Most people know that if they are having an emergency, they should not seek care at a convenience setting. Therefore, convenience settings like retail clinics often do not directly compete with EDs. Convenience settings do not save lives in emergencies; rather, they deliver services relating to minor ailments or give people peace of mind and reassurance that they are taking the right steps to get better. ¹⁹ Generally, the use of such supply-sensitive care is largely capacity-driven, which makes it potentially inconsistent with the move to value-based care and payment. In many instances, convenience settings simply create new use through improved access. ²⁰

Conditions for which patients typically visit retail clinics also constitute a large portion of reasons patients visit primary care providers. Therefore, there is a concern that retail clinics pose a financial threat to primary care providers by treating the latter's most profitable patients. ²¹ Others believe that retail clinics may increase primary care revenue by generating referrals to practices and by allowing physicians in practice settings to focus on sicker patients with more complex needs, which generally provides higher payment. This premise is supported by evidence that, while physician office visits for acute minor conditions have declined by 13 percent since the advent of retail clinics, total physician visits have remained steady. ²²

Retail clinics may have a role to play in providing timely and affordable access to primary care services. It is estimated that if the 20 percent of ED visits that are for low-level conditions could instead be treated in a retail clinic, the health care system would save an estimated \$4 billion annually.²³

CONFLICTS OF INTEREST

When the retail clinic market began, it was predominantly run by commercial retailers. More recently, traditional health care institutions have entered the market. ²⁴ Commercial retailers often affiliate with regional health systems leading to the co-branding of the retail clinic. In such a relationship, the health system affiliate and commercial retailer might develop protocols to support clinical decision-making and patients might be referred to the affiliate health system for primary care or ongoing care. ²⁵

Because retail clinics are often located within a store that includes a pharmacy, there is also concern that providers might overprescribe to induce unnecessary purchases at the store or provide discount plans for the pharmacy housing the retail clinic.

Retail clinics may also implicate a number of federal laws and regulations.²⁶ The federal Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving anything of value to induce or reward referrals for any item or service that is reimbursable, in whole or in part, by a federal health care program. The Anti-Kickback Statute may be activated if the retail clinic is owned by a host retailer wherein they refer federal health care program patients to one another. Retail clinics must

mitigate this potential risk by structuring an arrangement with the retailer to fit within the safe harbors. Additionally, retail clinics must consider the Stark Law, which prohibits physician selfreferral. Specifically, the law prohibits a referral by a physician of a federal health care program patient to an entity providing designated health services (DHS) if the physician has a financial relationship with that entity. While most retail clinics do not offer such DHS and therefore do not implicate the Stark Law, some clinics offering routine lab services, which are DHS, are subject to the Stark Law and must fit within specifically enumerated exceptions.

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LEGISLATIVE ACTIVITY

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There has been limited restrictive legislation passed regarding retail clinics at either the federal level or state level.²⁷ Aside from licensing the physician assistants, nurse practitioners, and other providers working at retail clinics, most states have not passed legislation specifically addressing retail clinics. 28 Rather, the clinics tend to operate within the existing state law framework. Importantly, there have been several noteworthy challenges to retail clinic regulation by the Federal Trade Commission (FTC), which is charged with preventing unfair methods of competition and unfair or deceptive acts of practice in or affecting commerce.²⁹ These FTC challenges expressed concerns over provisions that might cause undue burden to retail health clinics and have the effect of limiting their ability to compete. After the only two states to try and pass legislation imposing requirements specific to retail clinics were struck down by the FTC, there has not been much legislative activity in other states.

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RELEVANT AMA ACTIVITY AND POLICY

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With respect to scope of practice issues, the AMA has established a Scope of Practice Partnership with members of the Federation as a means of using legislative, regulatory, and judicial advocacy to restrain the expansion of scope of practice laws for allied health professionals that threaten the health and safety of patients.

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Store-based health clinics are consistent with long-standing AMA policy on pluralism (Policies H-165.920, H-160.975, and H-165.920). Most notably, the AMA supports free market competition among all modes of health care delivery and financing, with the growth of any one system determined by the number of people who prefer that mode of delivery, and not determined by preferential federal subsidy, regulations, or promotion (Policy H-165.985).

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AMA Policy H-160.921, established with Council on Medical Service Reports 7-A-06 and 5-A-07, outlines principles for store-based health clinics. The policy calls for an individual, company, or other entity establishing or operating a store-based health clinic to have a well-defined and limited scope of clinical services; use standardized medical protocols derived from evidence-based practice guidelines; establish arrangements by which their health care practitioners have direct access to and supervision by MDs/DOs; establish protocols for ensuring continuity of care with practicing physicians within the local community; establish a referral system with physician practices or other facilities for appropriate treatment if the patient's conditions or symptoms are beyond the scope of services provided by the clinic; inform patients in advance of the qualifications of the health care practitioners who are providing care, as well as the limitation in the types of illnesses that can be diagnosed and treated; establish appropriate sanitation and hygienic guidelines and facilities to insure the safety of patients; use electronic health records as a means of communicating patient information and facilitating continuity of care; and encourage patients to establish care with a primary care physician to ensure continuity of care. Additionally, Policy H-160.921 states that health insurers and other third-party payers should be prohibited from waiving or lowering

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copayments only for patients that receive services at store-based health clinics.

AMA Policy D-160.986 addresses the alliance of retail clinics with pharmaceutical chains. The policy directs the AMA to ask the appropriate state and federal agencies to investigate ventures between retail clinics and pharmacy chains with an emphasis on the inherent conflicts of interest in such relationships, patients' welfare and risk, and professional liability concerns. Additionally, Policy

D-160.986 directs the AMA to continue to work with interested state and specialty societies in developing guidelines for model legislation that regulates the operation of store-based health clinics and to oppose waiving any state or federal regulations for store-based health clinics that do not comply with existing standards of medical practice facilities.

 The AMA also has established policy that addresses the physician-patient relationship, physician extenders, and continuity of care. The AMA encourages policy development and advocacy in preserving the doctor-patient relationship (Policies H-100.971 and H-140.920). The AMA has extensive policy on guidelines for the integrated practice of physicians with physician assistants and nurse practitioners (Policies H-160.950, and H-360.987). Policy H-160.947 encourages physicians to be available for consultation with physician assistants and nurse practitioners at all times, either in person, by phone, or by other means. Policy H-425.997 encourages the development of policies and mechanisms that assure continuity and coordination of care for patients. Finally, the AMA believes that full and clear information regarding benefits and provisions of a particular health care system should be available to the consumer (Policy H-165.985). Addressing other possible retail clinic services that might impact continuity of care, Policy H-440.877 states that, should a vaccine be administered outside the medical home, all pertinent vaccine-related information should be transmitted back to the patient's primary care physician and that the administrator of the vaccine should enter the vaccination information into an immunization registry when one exists to provide a complete vaccination record.

 Finally, the AMA has extensive policy related to the health care team. Several policies reinforce the concept of physicians bearing the ultimate responsibility for care and advocate that allied health professionals such as nurse practitioners and physician assistants function under the supervision of a physician (Policies H-35.970, H-35.989). Policy H-160.912 advocates that all members of a physician-led team be enabled to perform medical interventions that they are capable of performing according to their education, training and licensure, and the discretion of the physician team leader. Policy H-160.906 defines "physician-led" in the context of team-based health care as the consistent use by a physician of the leadership, knowledge, skill, and expertise necessary to identify, engage, and elicit from each team member the unique set of training, experience, and qualifications needed to help patients achieve their care goals, and to supervise the application of those skills.

DISCUSSION

Retail clinics have had a steadily growing role in health care over the past decade. The Council recognizes concerns that the retail clinic model may potentially undermine the medical home and therefore the physician-patient relationship and quality of care. Nonetheless, the Council acknowledges the ease and convenience of retail clinics for minor acute conditions that has increased their prominence in the health care system. As such, the Council believes that, with the appropriate safeguards and guidelines, retail clinics have a complementary place in the delivery of health care. The following recommendations attempt to strike a balance between the use of retail clinics and traditional physician visits with the patient's best interest of paramount concern.

In 2006, the AMA established Policy H-160.921 regarding store-based clinics, another designation for retail clinics, when it became clear that the clinics were rapidly expanding and spreading across

the country. As previously noted, this policy articulates principles for store-based health clinics, and the policy remains highly salient today. Accordingly, the Council recommends reaffirming Policy H-160.921.

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Additionally, the Council suggests reaffirmation of numerous policies still relevant to the appropriate role of retail clinics and the practice of medicine. The Council recommends reaffirming Policy H-160.921 asserting that health insurers and other third-party payers should be prohibited from waiving or lowering copayments only for patients that receive services at store-based health clinics, and reaffirming Policy H-215.981 recognizing the potentially detrimental effects of the corporate practice of medicine. Further, the Council recommends reaffirming Policy D-35.985 on the physician-led health care team and Policy H-385.926 supporting physician choice of practice, which includes physicians wishing to practice in the retail clinic setting. Further, the Council remains concerned over proper vaccination reporting at retail clinics to avoid duplicative immunizations. To that end, the Council recommends reaffirming Policy H-440.877 stating that, should a vaccine be administered outside the medical home, all pertinent vaccine-related information should be transmitted back to the patient's primary care physician and entered into an immunization registry when one exists to provide a complete vaccination record.

For guidance on additional recommendations, the Council reviewed the American Academy of Family Physicians' (AAFP) position on retail clinics. Most recently, the AAFP developed a set of characteristics designed to guide discussions between the AAFP and retail clinics about how to collaborate for the good of patients.³⁰ The characteristics include using local physician medical directors, the timely transfer of medical records to the patient's primary care physician, and assisting patients in identifying a primary source of care in the community, among others. The Council found many of the articulated characteristics to be relevant and adapted a number of them for recommendation in this report.

The following recommendations build upon the AMA's current policy on store-based health clinics and reflect a cautious acceptance of retail clinics having a role to play in the health care system with the view that they are part of the continuum of care. Additionally, the Council approaches this issue with the belief that continuity of care and quality of patient care and outcomes are of overriding importance.

The Council recognizes that retail clinics have been playing an increasingly important role in the health care system and consequently garnering attention. Therefore, the Council will continue to monitor market-based developments in health care delivery including retail clinics.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 705-A-16 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-160.921 outlining principles for store-based health clinics and amend all references to "store-based health clinics" to "retail clinics" to reflect the current naming standard. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-215.981 regarding the corporate practice of medicine. (Reaffirm HOD Policy)

1 3. That our AMA reaffirm Policy D-35.985 supporting the physician-led health care team. 2 (Reaffirm HOD Policy) 3 4 4. That our AMA reaffirm Policy H-385.926 supporting physicians' choice of practice and 5 method of earning a living. (Reaffirm HOD Policy) 6 7 5. That our AMA reaffirm Policy H-440.877 stating that if a vaccine is administered outside the 8 medical home, all pertinent vaccine-related information should be transmitted back to the 9 patient's primary care physician and the administrator of the vaccine should enter the vaccination information into an immunization registry, when one exists, to provide a complete 10 11 vaccination record. (Reaffirm HOD Policy) 12 13 That our AMA supports that any individual, company, or other entity that establishes and/or 14 operates retail health clinics adhere to the following principles: 15 16 a. Retail health clinics must help patients who do not have a primary care physician or 17 usual source of care to identify one in the community; 18 19 b. Retail health clinics must use electronic health records to transfer a patient's medical records to his or her primary care physician and to other health care providers, with the 20 21 patient's consent; 22 23 Retail health clinics must produce patient visit summaries that are transferred to the 24 appropriate physicians and other health care providers in a meaningful format that 25 prominently highlight salient patient information; 26 27 d. Retail health clinics should work with primary care physicians and medical homes to 28 support continuity of care and ensure provisions for appropriate follow-up care are 29 made; 30 31 e. Retail health clinics should use local physicians as medical directors or supervisors of 32 retail clinics: 33 34 Retail health clinics should neither expand their scope of services beyond minor acute 35 illnesses including but not limited to sore throat, common cold, flu symptoms, cough, and sinus infection nor expand their scope of services to include infusions or 36 37 injections of biologic; and 38 39 Retail health clinics should have a well-defined and limited scope of clinical services, 40 provide a list of services provided by the clinic, provide the qualifications of the on-site health care providers prior to services being rendered, and include in any marketing 41 42 materials the qualifications of the on-site health care providers. (New HOD Policy) 43

7. That our AMA work with interested stakeholders to improve attribution methods such that

a physician is not attributed the spending for services that a patient receives at a retail health clinic if the physician could not reasonably control or influence that spending. (New

Fiscal Note: Less than \$500.

HOD Policy)

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