Target Audience

This white paper is addressed to three audiences who may be considering adoption or support of stand-alone e-prescribing as an efficiency and quality of care measure: (1) managers of ambulatory community health organizations, (2) physicians and medical groups, and (3) managers of healthplans. Many of the considerations in this paper are also relevant to e-prescribing that is integrated with an electronic health record system. This paper builds upon the Healthcare Information and Systems Society (HIMSS) book published this year on the factors impacting e-prescribing. The focus of this paper is how a physician or an organization decides if he/she/it desires to implement stand-alone e-prescribing.

Summary

Current prescribing practices are a weakness in the delivery of high quality medical care. Physicians write 4.5 billion new prescriptions annually and 1.5% to 4% of these contain errors. These errors cause 1 of every 131 deaths of ambulatory patients. Errors are caused primarily by communication of prescriptions: illegible handwriting, unclear abbreviations, dose errors, unclear oral orders, ambiguous orders and fax clarity. Electronic prescribing (e-prescribing) would require typed input, preferably from the physician, and would avoid most of these errors or allow them to be rectified online by the physician at the time of prescription writing.

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (commonly called the “Medicare Modernization Act”) began the Medicare Part D drug program. That law directed that healthplans sponsoring Part D drug programs begin supporting e-prescribing by May of 2009. The act also requires that physicians and pharmacies transmitting prescriptions electronically utilize standard transactions established under the act. While this is not a mandate to use e-prescribing throughout healthcare, by establishing a process, standards and timetable, many of the entities involved in prescribing are likely to adopt these practices, standards and the systems developed by vendors to support them.

Recently, a group of vendors and healthplans has developed what is called the National ePrescribing Safety Initiative or NEPSI. NEPSI is offering physicians software at no cost to perform e-prescribing. Because networks of pharmacies pay the connection cost, it is really possible for physicians to try and continue to use e-prescribing for “free”. An interface between the NEPSI system and any practice management system is available for about $300 and $20 per month from Hilgraeve, Inc., so that patient demographics need not be re-keyed into the e-prescribing system.

Given these market forces and opportunities, this white paper explores the key considerations of moving to e-prescribing in order to help a community or rural clinic, a physician, a physician group, or a health plan decide whether to consider this option. In
doing this, the reader is told about the results of recent e-prescribing pilots conducted by the Center for Medicare and Medicaid Services, about e-prescribing for controlled substances, about the entities who provide networks supporting e-prescribing, and about key elements of e-prescribing. The aim of this white paper is to provide a framework for knowledgeable consideration of the e-prescribing alternative. The last section of the paper lists pros and cons of e-prescribing applicable to the clinic or physician.

**Value of ePrescribing**

Physicians and clinicians write more than 4.5 billion prescriptions each year and the volume of prescriptions rises annually. Between 1.5% and 4% of prescriptions contain errors that have a potentially detrimental effect upon the patient. Adverse drug events (ADEs) occur in 5% to 18% of ambulatory patients. There are an average of 38 ADEs per physician per year of which 14 ADEs are preventable, including 42% of the most serious. One of 131 ambulatory patient deaths is due to medication error.

Errors result from a number of factors. The most frequent source of error is miscommunication between the provider and the pharmacist. Communication errors stem most often from illegible handwriting, unclear abbreviations and dose indications, unclear telephone or verbal orders, and ambiguous orders and fax-clarity problems. Unreadable or vague prescriptions result in pharmacists making over 150 million calls to physicians seeking clarification annually. Other sources estimate that there are approximately 900 million prescription-related telephone calls per year with 30% of prescriptions requiring callbacks. Estimates of the length of call-back calls are from 2 minutes to 10 minutes per call – a substantial amount of staff time given the number of callbacks.

The prescription process is more complex than it may at first appear to the patient. The physician may not have such information as: other medications the patient is taking, possible drug-to-drug interactions, the formulary of the patient’s healthplan, current treatment guidelines of the payer, and information on healthplan requirements for prior authorizations.

The potential value of e-prescribing is in three areas: (1) patient safety, (2) increased physician office efficiency and (3) reduced cost. The above discussion makes it clear that there a potentially significant increase in patient safety because e-prescribing produces completely legible prescriptions in which all elements of the physician’s intent are clear and compatible with the healthplan or payer formulary, other patient medications, patient allergies, etc.

Increased office efficiency is gained by the fact that the physician (or physician office worker) entering the prescription receives immediate feedback if a drug is not on the insurer’s formulary that applies to the patient, if there is a dosage error, etc. There is seldom a callback needed to determine what was intended. The prescription is immediately transmitted to the pharmacy, so the process is more convenient for the patient as well.

Healthplans have a potential appreciable cost savings from e-prescribing. There are expected improvements in formulary adherence which have been estimated from 14% to 88%. A healthplan which already manages its formulary well with its providers will have
a lower potential for improvement and a plan which manages its formulary loosely with respect to providers will have a large potential. Sierra Medical Associates, a large medical group, increased use of generics by 8.2% by adding e-prescribing. xi This is a significant savings to the healthplan. Another potential saving comes from enhancing the consistency with which formulary prior authorization requirements are observed and savings from medical care resulting from avoided ADEs.

**Medicare Modernization Act of 2003**

The Medicare Modernization Act of 2003 authorized the Medicare Part D drug program. Even though the act applies to a single federal program, it is likely to eventually drive transaction practices in almost all of healthcare. Doctors are not required by the act to prescribe electronically. The Medicare Modernization Act regulations do require that after 2009, physicians and pharmacies who/that prescribe electronically for Medicare Part D beneficiaries must utilize the final standards for transactions approved by the Center for Medicare and Medicaid Services (CMS) which are scheduled to be approved in April 2008. According to regulations, healthplans (Part D sponsors) are required to establish and maintain after 2009 an electronic prescription drug program that complies with transaction standards adopted by CMS. xii

**National ePrescribing Safety Initiative**

The National ePrescribing Safety Initiative (NEPSI) was developed by a group of vendors and healthplans which are committed to reduce medical errors and position themselves favorably in the healthcare market of the present and future. The organizations participating have agreed to offer stand-alone e-prescribing software at no cost to physicians for five years. After five years, those physicians and clinics not using an ERH will pay a per physician fee of $15 to $20 per month for use of the e-prescribing software. Pharmacies pay the cost of the prescribing networks. NEPSI has arranged that a third-party vendor will provide interfaces between its software (essentially, the Allscripts e-prescribing system from its TouchWorks EHR system) and physician practice management systems for a one-time fee (as of June 2007) of $299.

If a healthplan wishes to promote the NEPSI approach to its contacted physicians, the healthplan would currently incur some cost. In theory, this would be recouped through savings from higher use of generic medications, fewer member ADEs and their associated healthcare cost, and more efficient administration of medications requiring prior authorization.

The vendors and healthplans sponsoring NEPSI include Allscripts, Dell, three national or regional healthplans, five technology companies, SureScripts, Google, and a chemotherapy management organization. A list of sponsors is available at http://www.nationalerx.com/sponsors.htm.

**E-Prescribing Pilot Implementations**
Part of the sequence of e-prescribing standards development under the legislation was a pilot of e-prescribing standards. The Secretary of Health and Human Services, Michael Leavitt, reported these results on schedule in April 2007.xiii

That demonstration involved the use of the standards specified under the Medicare Modernization Actxiv. Based on the recommendation of the National Committee on Vital and Health Statistics (NCVHS), CMS adopted a set of foundation standards for e-prescribing. The term “foundation standards” was used because they do not support the full range of e-prescribing functionality, but they are a base on which other standards can be built. These foundation standards were initially four but after public comment were reduced to three:

1. Eligibility and benefits information, including the drugs included in the applicable formulary, and tiered formulary structure, and any requirements for prior authorization.

2. The following information with respect to the prescribing and dispensing of a covered Part D drug:
   a. Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warning or cautions, and, when indicated, dosage adjustments; and
   b. Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

3. Information that related to the medical history concerning an individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

For the pilots, the Secretary and NCVHS eventually focused on six elements of the foundation standards:

1. **Formulary and benefits information**, National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard Version 1.0. Displays the formulary status and alternative drugs as well as co-pays and other status information. NCPDP has developed a standard using RxHub protocol. This transaction was used in conjunction with the eligibility request and response transaction, Accredited Standards Committee (ASC) X12N 270/271.

2. **Exchange of medical history**, NCPDP SCRIPT Standard Version 8.1 (updated during the pilots from Version 5.0). Includes the status, provider, patient, coordination of benefits, request and response segments of SCRIPT. Few physicians in the demonstrations actually accessed prescription history data. Many may not have known that it was available.

3. **Fill status notification**, NCPDP SCRIPT Version 8.1. Informs when Rx is filled, not filled, or partially filled. Includes provider, patient and drug segments of SCRIPT message. Not yet widely used as the majority of pharmacy systems either do not have this feature or have not implemented it.
4. **Prior authorization messages**, ASC X12N 278, Version 4010A1 and ASC X12N 275, Version 4010 with HL7. Requires header information, requester, subscriber, utilization management, and other relevant information for prior authorization requests. This transaction is not widely implemented and while it could be useful to simplify the overall prior authorization system, it is not technically able to support the complex nature of the prior authorization process.

5. **Structured and Codified SIG** (The “signature” section of prescription contains directions to the patient, often abbreviated “sig.”, so as not to confuse the instructions with the provider’s signature, which is also there.), NCPDP SCRIPT Standard Version 8.1 and Structured and Codified SIG Standard Version 1.0. Indication, dose, dose calculation, dose restriction, route, frequency, interval, site, administration time, duration and stop-order instructions. There is no standard format or vocabulary for SIGs leaving room for misinterpretation and error.

6. **Clinical drug terminology (RxNorm)**. A clinical drug nomenclature developed by the National Library of Medicine that provides standard names for clinical drugs and for dose forms as administered. It also provides links from clinical drugs to their active ingredients, drug components, and most related brand names. This nomenclature is promising but does not always link properly currently, requires the use of intermediary knowledge-based products, and does not handle pharmacy-compounded drugs.

Five applying pilot sites became grantees of CMS to test the above standards. The Agency for Healthcare Research and Quality’s (AHRQ) National Resource Center for Health Information Technology (NRC) evaluated the efforts of the pilot sites. AHRQ/NRC concluded that the first three standards elements were technically able to convey the information needed to support its functions for use in Medicare Part D programs. The later three standards elements were found by AHRQ/NRC not to be ready for use. The comments in the above list indicate the reasons they were not accepted.

Like the Health Insurance Portability and Accountability Act (HIPAA), the Medicare Modernization Act contains a preemption clause indicating that the Act preempts conflicting state e-prescribing regulations. It appears that this clause may not be used aggressively by the federal government.

**E-Prescribing for Controlled Substances**

The Drug Enforcement Administration (DEA) of the U.S. Department of Justice, regulates and enforces the prescribing of controlled or scheduled drugs. The Controlled Substances Act is Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The Controlled Substances Act places all controlled substances into one of five schedules based on medical use, potential for abuse and safety or potential for dependence. The DEA has responsibility for classification in these schedules, and it reclassifies drugs from time-to-time. Substances in Schedule I have no medical use and high potential for abuse. Drugs in Schedules II through V have a medical use and higher-numbered schedules have less potential for abuse.
Currently, the DEA does not allow e-prescribing for controlled substances. DEA regulations require that the pharmacist must have the original physical signed prescription slip prior to dispensing Schedule II controlled substances, with exceptions for emergency prescribing and long-term care facilities. Prescriptions for Schedule III and IV substances can be transmitted orally but must be written out by the pharmacist prior to filling. There appears to be no DEA requirement that prevents e-prescribing of Schedule V substances. State laws and practices may be more stringent than DEA regulations for any schedule. Hereafter we do not distinguish Schedule V form Schedules III and IV.

The DEA has been drafting proposed rules for e-prescribing for several years. A Notice of Proposed Rulemaking for the Electronic Prescribing of Controlled Substances (EPCS) was to be published in the Federal Register in 2003 but has not yet appeared. A two-day hearing on the need for these regulations was conducted in July, 2006, by the DEA and the U.S. Department of Health and Human Services to solicit public testimony.

Until the DEA issues rules for EPCS, prescriptions can be transmitted by written prescription, by verbal order or by facsimile (via fax machine). The general practices of prescribers are as follows:

1. For Schedule II drugs, the physician may call-in or fax the prescription to the pharmacy but the pharmacist must receive the original written and signed prescription before dispensing the prescription. (There are exceptions for emergencies, for long-term care facilities and for parenteral products.)

2. For Schedule III through V drugs, an original prescription signed by the physician and faxed to the pharmacy is considered a legal “oral” prescription. This may be accomplished four ways in conjunction with e-prescribing:
   a. Hand-write and sign the prescription and fax it to the pharmacy.
   b. E-prescribe these prescriptions, print and sign the prescription, and fax it to the pharmacy. (Pharmacy receives two copies, one e-prescribed and one faxed.)
   c. E-prescribe these prescriptions, print and sign the prescription, and have the patient take it to the pharmacy.
   d. E-prescribe these prescriptions and require the pharmacist to call the physician office to verify the prescription and log who verified it.

If a prescription is generated by an electronic device (PC, fax server, handheld device, cellular telephone, etc.) and either (a) is not signed or (b) contains an electronic signature, the prescription is not considered legal by the DEA. The EPCS regulations are expected to provide further options.

Entities Supporting E-Prescribing
For e-prescribing to function well, the prescribing physician’s software needs to connect to a server or network that connects to all the pharmacies in the physician’s area that a patient might prefer to use. Since patients may travel extensively and have a home in one location and vacation far away, national networks have been developed. All of the organizations mentioned below offer bi-directional networks: A pharmacy may send a transaction to a pharmacy and may receive information back from the pharmacy that the prescription was filled, partially filled, or not filled, for example. There are two types of networks of interest: networks of pharmacies and networks of prescription benefit management (PBM) companies.

**Pharmacy networks.** As used here, a pharmacy network is an entity that has electronic access to many pharmacies in the U.S. for the purpose of e-prescribing and other pharmacy transactions such as claims submission. There are currently three pharmacy networks: SureScripts, NDCHealth and Emdeon.

**SureScripts** was founded in 2001 by the National Association of Chain Drug Stores and the National Community Pharmacists Association, the latter composed of independent community pharmacies. SureScripts now has agreements with 95% of retail pharmacies in the U.S. for connection to its network. On May 1, 2007, SureScripts announced the acquisition of the ProxyMed/MedAvant's pharmacy network, until then one of the four largest pharmacy network.

**NDCHealth** grew out of a history of transaction processing for healthcare organizations. It provides claims processing and transaction services to 30,000 pharmacies and indicates a network connections to 80% of U.S. pharmacies.

**Emdeon** is the relatively new name of the merged entities Healtheon and WebMD, which merged in 1999. Emdeon provides a pharmacy network of unknown size, an e-prescribing product, and various pharmacy services.

Pharmacy networks typically charge a per-transaction fee for each transaction sent or received. In most cases, the pharmacy involved pays the fee to encourage the prescriber’s patient to use that pharmacy.

**Pharmacy benefit management network.** There is a single major presence in this discipline, RxHub. RxHub was formed in 2001 by three PBMs: Advance PCS, Express Scripts and Medco Health Solutions. RxHub is designed to be attractive to other PBM besides the founders but PBMs outside the three founders of RxHub have been slow to join. The function of a PBM network is to allow prescribers to have access to prescription history, formularies, and other data that a PBM has available for a member served by a payer using that PBM. The pharmacy network vendors listed above are also attempting to capture the same information by tracking prescriptions filled and obtaining formularies either directly or through an intermediary such as Epocrates, which provides formularies for downloading to computers and personal digital assistants.

**Elements of E-Prescribing**

**Core components.** The prescribing components of e-prescribing can be grouped into core prescription capabilities, healthplan information and clinical alerts. The core components of e-prescribing are:
1. Medication lists searchable based on:
   a. Trade and generic availability
   b. Alphabetic listing of medications
   c. Diagnoses
   d. Therapeutic categories
   e. Physician favorites (most commonly prescribed medications)
2. Medication lists which include available dosage forms, strengths, route, frequency, duration (which together indicate quantity)
3. Directions to patients (SIG)
4. Prescriber’s signature
5. Number of authorized refills
6. DAW (dispense as written) or substitution permitted
7. Field for comments to pharmacist
8. PRN (as needed) field

Healthplan information. These data elements, known to the member’s healthplan, are necessary for prescribing and billing. Data elements include:
1. Member eligibility
2. Applicable formulary
3. Prior authorization requirements for certain medications (included in the formulary)
4. Medication history
All of these data may be provided through RxHub, if the healthplan or PBM contract with that entity. Alternatively, the member’s healthplan may provide these data to the vendor of e-prescribing software or make arrangements to provide them to the pharmacy network vendor.

Clinical alerts. A member’s demographics and medical history may indicate that a pharmaceutical will interact with the patient in an undesirable way. Some such situations include:
1. Drug-drug interactions
2. Drug-allergy or sensitivity
3. Drug contraindicated due to a patient condition
4. Age-specific warnings for pediatric and geriatric patients, for example
5. Dose adjustment needed for patient weight
If the flow of information to the prescriber includes lab information:
6. Drug-lab interactions
7. Lab values to monitor with medication(s)
8. Adjustments for patient lab results
If the member data includes electronic health record (EHR) information:
9. Consideration of pregnancy or lactation
An e-prescribing system may include drug reference materials such as the Physician’s Desk Reference (PDR) and potential access to other guidance. If an e-prescribing system is part of or interfaced to an EHR, the system may have access to full member medical histories. Because this paper is focused on stand-alone e-prescribing systems, we only mention more extensive e-prescribing approaches.

When a clinical or other prescribing alert occurs, the prescriber should be able to determine the rationale for the alert (observed drug interaction, report of patient, non-formulary drug, etc.) and clinical alerts should be prioritized based on potential severity
and likelihood of the problem. Prescribers should be able to overrule an alert based on experience with the patient.

What Do Users Say About E-Prescribing?

To determine what users say about stand-alone e-prescribing, we interviewed two early adopters of the NEPSI solution, both of whom began use of the system in February 2007. One is a family practitioner in a small rural town in upper Michigan and the other is a pediatric allergist practicing in Philadelphia. Both were provided as references by the NEPSI program.

Rural family practice. The rural practitioner does not yet have eRx Now linked to his practice management system as he is in the process of implementing a new practice management system. Nurses or office staff enter the demographics of patients to be seen the next day into the e-prescribing system and he enters data on same-day patients, which he says is quick when it is necessary. There is little managed care in his market so obtaining formularies is not a priority. He does use Epocrates to view some formularies, but it is not linked to his system. He uses the e-prescribing system either on his desktop computer or through a Pocket PC smart phone.

The local Wall Mart and a large pharmacy are equipped to receive e-prescriptions but most pharmacists have not warmed to handling refills through the system yet. E-prescriptions to other local pharmacies are converted by NEPSI and go to rural pharmacies as faxes. The physician uses the option of prescribing by diagnoses, which builds both a diagnosis history for each patient and a list of favorite medications by diagnosis. To benefit from the drug-drug and allergy alerts requires substantial up-front data entry and he is not using those functions yet. He uses e-prescribing for all patients but prescriptions for controlled substances and mail order pharmacies need to be printed out and signed. Patients send the printed prescriptions to the mail-order pharmaceutical providers.

To date, he has written about 1,000 e-prescriptions and has had only 4 fail, for which he needed to follow-up by telephone with the pharmacy. He particularly likes being able to handle refills online for those pharmacies that are learning to do it and the ability to prescribe for a patient anywhere in the country when they are traveling.

Urban pediatric allergist. This specialist does not have her practice management system linked to the e-prescribing system. When a current practice management upgrade is completed, the systems will be linked. Staff enter demographics on patients the day before appointments. E-prescriptions are sent to drug stores and refills are received from the pharmacies, an appreciated feature. There is only one significant healthplan in the market, which has an 85% market share. Its formulary is not available electronically. She uses a laptop at a central location near the sample closet to enter prescriptions, convenient as she provides samples to many patients.

She does not much use alerts yet as it takes time to build a pharmaceutical history in the system unless one takes the time to enter historical data up front. She is a solo practitioner so she sees only her own prescriptions in the system. She uses the system for 100% of prescriptions but she prints out slightly more that 50% as patients with
chronic diseases use mail order pharmacies and they are not yet able to accept e-prescriptions.

There are no problems in communicating instructions to pharmacies or with SIGs. In the early months, some features of the system were tweaked to enhance these abilities. There is a substantial list of reports available from the system, for example, to show patients who were prescribed a medication that has been recalled or to show a patient medication history. An important factor in e-prescribing success is adapting the office workflow to support the process.

**Observation.** These two examples demonstrate an interesting feature. Although we document many potentially automated features such as formulary compliance and clinical alerts, these physicians are effectively using limited forms of e-prescribing and are pleased with the features offered over prior manual script writing.

**Is E-Prescribing Right for Me?**

So what are the pros and cons of e-prescribing for a clinic, a physician or a practice at this time? There are a number of factors to consider:

**Pros.** There are a number of favorable factors:

1. **Regulation.** The Medicare Modernization Act will result in greater support for e-prescribing after May of 2009. This does not mean that e-prescribing will suddenly become the most common approach to prescribing, but it will likely mean that more and more providers will try and eventually adopt e-prescribing.

2. **Office efficiency.** At the point of change, practice efficiency may not immediately rise, but over time, the ability to prescribe in a clear and unambiguous way, considering the member’s formulary and other medications, speeding processing of refill requests, and reducing callbacks will generate efficiency.

3. **Patient safety.** Increasing patient safety by clarity and consideration of other patient conditions, allergies, medications, etc., will eventually reduce malpractice premiums and the embarrassment and legal exposure of prescribing errors. An e-prescribing system will provide the physician with data on use of prescriptions (refills) so the physician can assess patient progress knowledgably.

4. **Patient satisfaction.** Members will be please with faster transmission of prescriptions to the pharmacy and will notice the fact that the prescribing physician has new information available at the time of prescribing. There will be fewer hassles due to prescribing of medications not on the member’s formulary.

5. **Cost.** The physician will eventually enjoy savings based on office efficiency, less exposure to malpractice claims, and, with some healthplans, a share of the savings from prescribing more generics and less non-formulary drugs.

**Cons.** There are some negatives to be considered as well:
1. **Practice patterns and adoption.** Medicine is made up of many different individual physicians. Some are not highly interested in changing anything about practice patterns unless there is a clear and immediate time or cost savings. Others have grown up with computers and see that the computer-aided future is around the corner. They are ready to make some effort to meet the future halfway. There is no question that adoption is the biggest hurdle to e-prescribing. While there are some 150,000 physicians nationally who have the ability to e-prescribe, less than 3% of all prescriptions are electronic. xxii (There are on the order of 650,000 patient care physicians in the U.S.) xxiii

2. **Developmental processes.** While many parties support the idea of stand-alone (and integrated) e-prescribing, the processes are not yet completely refined. As the results of the CMS pilot tests indicate, some data cannot be transmitted unambiguously using standard formats. (It can be transmitted in narrative form but this is not ideal for computers as data cannot be identified by being in a designated field.) By the same token, if medicine waited for a way to unambiguously code medical records data without narrative, the practice of medicine might not begin for another century.

3. **Developmental networks.** Although SureScripts connects to 95% of all pharmacies on paper, a prescriber may sometimes find a local pharmacy of a connected chain or an independent pharmacy that is not yet listed in the system. These are problems that can be worked with some phone calls and emails.

4. **Dependency on a system.** The downside of depending on systems is that systems do go down and one needs to have a workaround or revert to manual systems when this occurs.

5. **Privacy concerns.** Some believe that electronic modalities produce a new risk that patient data will be compromised. With paper methods, the possibility of one patient record being compromised was probably greater than with electronic systems. The source of concern with electronics is that there is a possibility that many records can be inadvertently or purposely compromised. Sound privacy safeguards are crucial.

In summary, there are strong forces driving medicine toward electronic processes. E-prescribing is on the leading edge of this wave and is for physicians now a largely non-economic good as the cash price is zero. The real decision a physician must make is whether he or she wants to try the new technology. Given the low cost of entry, e-prescribing, unlike adopting an EHR, can be tried on a pilot basis and then adopted or not. With NEPSI, there is really a “free trial”. To carefully assess e-prescribing, a physician probably wants to have in place the practice management interface for demographics so that s/he can e-prescribe for all patients, not just those of a single payer.

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