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June 3, 2019

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

RE: Medicare and Medicaid Program; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in Federally-facilitated Exchanges and Health Care Providers (CMS-911-P)

Via electronic submission: [www.regulations.gov](http://www.regulations.gov)

Dear Administrator Verma:

Thank you for the opportunity to provide feedback on the Medicare and Medicaid Program; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in Federally-facilitated Exchanges and Health Care Providers proposed rule.

As you know, the American Health Information Management Association (AHIMA) is the national non-profit association of health information management (HIM) professionals. Serving 52 affiliated component state associations including the District of Columbia and Puerto Rico, AHIMA represents over 103,000 health information management professionals with the mission of empowering people to impact health. AHIMA's credentialed and certified HIM members can be found in more than 40 different employer settings in 120 different job functions—consistently ensuring that health information is accurate, timely, complete, and available to patients and clinicians.

Our comments and recommendations of certain sections of the proposed rule can be found below.

**Request for Comment – “Interoperability” Activities as Alternatives to Measures in the Promoting Interoperability Program**

AHIMA supports CMS' approach to establishing “interoperability activities” in the FY2020 IPPS/LTCH PPS rulemaking which could serve as alternatives to measures in the Promoting Interoperability Program. Along these lines, we recommend that ONC consider note sharing as an “interoperability activity” for which eligible hospitals and critical access hospitals (CAHs) could receive credit in lieu of reporting the Provider to Patient Exchange measure. Studies conducted since the original OpenNotes demonstration project in 2010 continue to validate the project's original findings that note sharing increases patient

engagement, helping patients take better care of themselves without creating additional anxiety.<sup>1</sup> Other studies indicate that OpenNotes improves medication adherence.<sup>2</sup> Further, studies demonstrate that sharing clinical notes in real time increased communication between the patient and their clinician, allowing for more substantial communication beyond brief one-on-one encounters.<sup>3</sup> Patients also report increased insight into their conditions(s), citing more control of their healthcare and greater appreciation for the clinician.<sup>4</sup> Note sharing also enhances patient safety by allowing patients the opportunity to identify and ask for corrections in the clinical notes. At the same time, evidence suggests that physician fears that opening clinical notes would require additional time has not materialized with one study finding that fewer than 20 percent of physicians reported taking more time to document notes and some physicians framing such efforts as “better documentation—a good thing.”<sup>5</sup> However, despite this mounting evidence, note sharing is not universal, and even leading institutions are reluctant to implement the concept in practice. Today, less than 10 percent of the nation’s 5,000 hospitals engage in note sharing. Ultimately, AHIMA believes the best measure of whether a patient is successful in gaining access to their health information turns on whether the information provided to the patient is in fact meaningful and relevant to the patient. Designating note sharing as an “interoperability activity” could meaningfully enhance patient access to their health information without causing undue administrative burden on clinicians.

### **III. Patient Access Through APIs**

In general, AHIMA is supportive of CMS’ proposal under the rule to enable patient access to claims and encounter data as well as other plan data via openly published APIs. AHIMA continues to champion efforts that enhance the ability of patients to gain access to their health information under HIPAA while improving workflow of health information professionals. That said, it is unclear from the proposed rule whether a payer has an obligation to provide open API access to reopened and revised claims. For example, a contractor conducts a reopening to revise an initial determination or redetermination that a payer has already permitted a third-party application to retrieve with approval of the enrollee. What is the duty of the payer to provide open API access to the revised determination or decision? Will the payer be required to notify the enrollee prior to permitting a third-party app to retrieve the data? Does liability attach to the payer if it does not notify the third-party app of the revised determination? Is the payer required to provide open API access to the revised determination within the same timelines set forth for claims activity under the proposed rule? Would the clock start as soon as the revised determination or decision occurs? We recommend that CMS provide greater clarity in the preamble or via subregulatory guidance as to how such instances should be managed by plans.

#### **h. Enrollee and Beneficiary Resources Regarding Privacy and Security**

AHIMA supports CMS’ proposal to require MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities and QHP issuers in FFEs to make available to

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<sup>1</sup> Mishra V, Hoyt R, et al. Qualitative and Quantitative Analysis of Patients’ Perceptions of the Patient Portal Experience with OpenNotes. *Appl Clin Inform.* 2019; 10(01): 010-018. Published 2019 Jan.

<sup>2</sup> Wright E, Darer J, Tang X, et al. Sharing Physician Notes Through an Electronic Portal is Associated with Improved Medication Adherence: Quasi-Experimental Study. *J Med Internet Res.* 2015;17(10):e226. Published 2015 Oct 8.

<sup>3</sup> Grossman LV, Creber RM, Restaino S, Vawdrey DK. Sharing Clinical Notes with Hospitalized Patients via an Acute Care Portal. *AMIA Annu Symp Proc.* 2018;2017:800-809. Published 2018 Apr 16.

<sup>4</sup> Id.

<sup>5</sup> Delbanco, Tom, et al. Inviting Patients to Reach Their Doctors’ Notes: A Quasi-experimental Study and a Look Ahead. *Ann Intern Med.* 2012; 157(7):461-470. Published 2012 October 2.

current and former enrollees certain information about factors to consider in selecting a health information management application, practical strategies to help safeguard the privacy and security of their data and how to submit complaints to the Office for Civil Rights (OCR) or the Federal Trade Commission (FTC). Such notice is critical in helping patients understand their rights under HIPAA and the Federal Trade Commission (FTC) Act.

AHIMA recognizes that the Office for Civil Rights has stated that if a patient's app was not provided by or on behalf of a covered entity, the covered entity will not be liable under HIPAA for any subsequent use or disclosure of ePHI received by the app.<sup>6</sup> However, we are concerned that as currently proposed, the rule does not include sufficient guardrails around HIPAA non-covered entities to protect the privacy and security of a patient's health information. Patients may be unaware that once they authorize a covered entity to push their health information to a third-party app and such an entity is a HIPAA non-covered entity, the rights afforded under HIPAA no longer apply. Additionally, patients may be unaware of how an app intends to use their health information, leaving them to the mercy of the app developer's terms of service and/or privacy policy unless an act on the part of the app developer meets the "unfair or deceptive acts or practices" standard under the Federal Trade Commission (FTC) Act. In fact, a recent cross-sectional study of 36 top-ranked apps for depression and smoking cessation revealed that only 16 apps described secondary uses.<sup>7</sup> 81 percent of the 36 apps transmitted data for advertising and marketing purposes to two commercial entities, Google and Facebook, but only 43 percent transmitting data to Google and 50 percent transmitting data to Facebook disclosed this.<sup>8</sup> Failure to provide appropriate and transparent privacy and security safeguards and/or lack of flexibility in allowing actors to perform due diligence could invite opportunities for "bad actors" to enter the market and potentially use such sensitive data for nefarious activities. Along these lines, we ask that CMS work with ONC to include as part of the certification criterion that API Technology Suppliers be required to verify an app's "yes/no" attestation to: (1) industry-recognized guidance such as [Xcertia's™ mHealth App Guidelines](#), (2) transparency statements and best practices including the [Federal Trade Commission's Mobile App Developers: FTC Best Practices](#) and/or the [CARIN Alliance's Code of Conduct](#) and (3) the adoption of either [ONC's Model Privacy Notice](#) or a notice in plain language with substantially the same content as described in ONC's Model Privacy Notice. Upon issuing a "yes" attestation, a health IT developer could in turn whitelist the app for use by an API Data Provider. We believe such a "light touch" attestation would not interfere with a provider's use of their acquired API technology and enhance a health IT developer's responsibility to patients. We also believe that such a requirement is consistent with enabling patient access to their EHI via an API-enabled app "without special effort" as this would not impose substantial additional costs or access requirements that may impede a patient's ability to access their information in a persistent manner.

#### **V. Health Information Exchange and Care Coordination Across Payers: Establishing a Coordination of Care Transaction to Communicate Between Plans**

In general, AHIMA supports CMS' proposal to require Medicare Advantage (MA) plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs to exchange, at a minimum, the

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<sup>6</sup> Available at: <https://www.hhs.gov/hipaa/for-professionals/faq/572/does-a-hipaa-covered-entity-bear-liability.html>.

<sup>7</sup> Huckvale K, Torous J, Larsen ME. Assessment of the Data Sharing and Privacy Practices of Smartphone Apps for Depression and Smoking Cessation. *JAMA Netw Open*. 2019;2(4):e192542. doi:10.1001/jamanetworkopen.2019.2542.

<sup>8</sup> Id.

USCDI at an enrollee's request at specific times. We believe that such a requirement is crucial in helping to establish a more longitudinal record for a patient. That said, we offer the following recommendations to improve upon the rule as currently proposed.

First, we recommend that CMS establish a clear deadline by which a payer should provide the USCDI data set to another plan upon an enrollee's request. It is unclear from the proposed regulation how much time a plan has to accommodate such a request and we are concerned that delays beyond the normal bounds of HIPAA would have a deleterious effect on care coordination and patient care. Along these lines, because such a request is patient-directed, we recommend that plans be required to send such information no later than 30 days from receiving the individual's request as required under HIPAA. If a plan is unable to provide access within 30 calendar days, we also recommend that the plan be able to extend the time by no more than 30 additional days in accordance with HIPAA. We believe this requirement would be consistent with HIPAA and help ensure that plans, clinicians, and patients have access to timely information for care coordination purposes.

Second, we recommend that CMS clarify that the five-year timeline proposed under the rule will not alter existing federal and state record retention laws. Federal and state record retention laws vary in terms of how long certain records must be retained and the types of information that should be retained.<sup>9</sup> For example, while many state laws vary in terms of how long the records of minors should be retained, most require the records to be retained longer than five years. Establishing a five-year period in which a plan must send or accept the USCDI without clarification as how this might impact federal and state record retention requirements might be construed as establishing de facto retention requirements for plans covered by the proposed rule. We recommend that CMS make clear that the five-year lookback period would not make any changes to existing federal and/or state record retention laws. We also recommend that CMS consider, as part of this proposed rule, what obligations a plan has in acting on a former enrollee's request to send the USCDI if the plan chooses to leave the market—will it still be required to send the data set? Is there a window after announcing its departure from the market that current and former enrollees will have to be able to request that the USCDI be sent to a plan that currently covers the enrollee? What type of notice to former enrollees would accompany such an announcement? We recommend that CMS provide additional guidance around such circumstances to assist enrollees in making sure that they can send the data set to their current plans as well as ensure the completeness of their health history.

Finally, we recommend that CMS provide greater clarity around what it means to "incorporate" the data set into the recipient plan's systems under the proposed rule. We agree with CMS that the provision of the USCDI will provide patients with a more comprehensive history of their medical care to assist them in making better informed healthcare decisions. However, as noted in our comments to ONC on its *21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* proposed rule, we are concerned that the USCDI does not correlate to content exchange standards and implementation specifications and that the lack of such standards and implementation specifications will compound existing difficulties in exchanging electronic health information. Expertise in data quality, integrity, and data stewardship positions HIM professionals well to address the incorporation of this data set and error reconciliation. However, additional clarification is needed from CMS as to its intention in requiring plans to incorporate the USCDI into a recipient plan's systems.

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<sup>9</sup> AHIMA. "Retention and Destruction of Health Information." (Updated October 2013). Available at: <http://library.ahima.org/PB/RetentionDestruction#.XLjibQ1VKipo>.

## **X. Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals (CAHs)**

Historically, AHIMA has been supportive of revisions to the current Conditions of Participation (CoPs) to advance the electronic exchange of information to support safe, effective transitions of care between hospitals and community providers. However, we have concerns related to CMS' proposal under this rule to require hospitals, psychiatric hospitals, and CAHs to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another healthcare facility or to another community provider. For example, in some instances, a hospital's electronic patient event notification (ADT) system is connected to its registration system and does not interact with the hospital's EHR. Therefore, requiring hospitals, psychiatric hospitals and CAHs under the CoPs to send ADT data when their EHR lacks such functionality is problematic. For that reason, we recommend that prior to the implementation of this provision under the Conditions of Participation, CMS should work with ONC as part of ONC's Health IT Certification Program, to require, as a condition of certification, that health IT systems be properly certified to send and receive ADT data.

AHIMA is also concerned about the lack of definition around "patient care team members" under the proposed rule. We agree with CMS that there are various methods by which hospitals and their partners may identify appropriate recipients. However, we are concerned about the operational costs associated with maintaining and updating a care team list that would most likely have to be created and updated with each patient admission. Furthermore, if CMS intends to construe the definition of "patient care team members" broadly, we believe it should take into account the potential physician burden in receiving ADT notifications at the time of admission and either prior to or at the time of discharge or transfer for each of their patients. Similarly, we are concerned that the phrase, "established care relationship with the patient relevant to his or her care" lacks clarity under the proposed rule. Would this include both past and present established care relationships with the patient? Would the established care relationship pertain to the patient's care in general or the specific diagnosis for which the patient was admitted? Given these concerns, we recommend that CMS constrain the term "established care relationship" to one that is current and directly related to the patient's diagnosis for which the notification is sent. Such clarification will help to limit the scope of the notifications being sent and received to those primarily responsible for the care of the patient.

## **XIII. Request for Information on Policies to Improve Patient Matching**

AHIMA supports CMS' intent to leverage its programmatic authority to improve patient identification to facilitate improved patient safety, enable better care coordination, and advance interoperability. Today, there is no consistent approach to accurately matching a patient to their health information which has led to significant costs to hospitals, health systems, physician practices, long-term, post-acute care (LTPAC) facilities, and other providers. According to a 2016 study of healthcare executives, misidentification costs the average healthcare facility \$17.4 million per year in denied claims and lost revenue.<sup>10</sup> Lack of a consistent and accurate approach to patient matching has also hindered the advancement of health information exchange across the care continuum. A 2017 study by the American Hospital Association indicates that 45 percent of large hospitals reported that difficulties in accurately identifying patients across health information technology (health IT) systems limits health information

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<sup>10</sup> 2019 National Patient Misidentification Report, Available at: [https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report\\_121416.pdf](https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report_121416.pdf).

exchange.<sup>11</sup> More importantly, there are patient safety implications when data is matched to the wrong patient and when essential data is lacking from a patient's record due to identity issues. Patient matching errors can often begin at registration and can generate a cascade of errors including wrong-site surgery, delayed or lost diagnoses, duplicative testing, and wrong patient orders. According to the *2016 National Patient Misidentification Report*, 86 percent of respondents said they have witnessed or know of a medical error that was the result of patient misidentification.<sup>12</sup>

We offer the following comments in response to the questions posed by CMS under this Request for Information (RFI).

- (1) Should CMS require Medicare FFS, MA Plans, Medicaid FFS, Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP FFS, CHIP managed care entities and QHP issuers in FFEs (not including SADP issuers) use a patient matching algorithm with a proven success rate of a certain percentage where the algorithm and real world processes associated with the algorithm used are validated by HHS or a 3<sup>rd</sup> party?***
  
- (2) Should CMS require Medicare FFS, the MA Plans, Medicaid FFS, Medicaid managed care plans, CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs to use a particular patient matching software solution with a proven success rate of a certain percentage validated by HHS or a 3<sup>rd</sup> party?***

Our answers to Questions #1 and #2 are the same. The use of sophisticated technologies including advanced patient matching algorithms and patient matching software solutions are crucial to improving patient matching. However, even the most advanced technologies cannot eliminate the risk of human error. For that reason, data governance and data quality improvement policies and procedures are fundamental to improving overall patient matching rates and data integrity in general. Rather than choosing to solely adopt a specific technological approach (i.e., patient matching algorithm, patient matching software solution, biometrics, etc.) we recommend that CMS also consider, at a minimum, requiring Medicare FFS, the MA Plans, Medicaid FFS, Medicaid managed care plans, CHIP FFS, CHIP managed care entities and QHP issuers in FFEs to annually evaluate their patient demographic data management practices using the Office of the National Coordinator (ONC)'s Patient Demographic and Data Quality (PDDQ) Framework. Plans could also be required to submit to CMS its scores in the five PDDQ process areas—data governance, data quality, data operations, platform and standards, and supporting processes—to demonstrate its overall data management practices. Such an approach would not require CMS to adopt one technology approach over another and provide plans with the flexibility to continue to adopt technology solutions that best meets their needs. Such a requirement would also be consistent with the Minimum Required Terms and Conditions (MRTC) under Draft 2 of the Trusted Exchange Framework and Common Agreement as currently proposed by ONC.<sup>13</sup>

AHIMA also recommends that CMS consider working with ONC to develop a voluntary set of agreed-upon metrics to evaluate algorithm performance across the industry. Such benchmarking will help shed further

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<sup>11</sup> AHA, Trendwatch: Sharing Health Information, Available at: <https://www.aha.org/system/files/2018-03/sharing-health-information.pdf>.

<sup>12</sup> 2019 National Patient Misidentification Report, Available at: [https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report\\_121416.pdf](https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report_121416.pdf).

<sup>13</sup> Available at: <https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf>.

light on the extent of the variation in matching algorithms and offer health IT developers an opportunity to improve upon their algorithms. We believe any set of agreed upon metrics should be developed by the industry in partnership with CMS and ONC.

**(3) Should CMS expand the recent Medicare ID card efforts by requiring a CMS-wide identifier which is used for all beneficiaries and enrollees in healthcare programs under CMS administration and authority, specifically by requiring any or all of the following:**

- **That MA organizations, Part D prescription drug plan sponsors, entities offering cost plans under section 1876 of the Act, and other Medicare health plans use the Medicare ID in their plan administration**
- **The State Medicaid and CHIP agencies in their FFS or managed care program use the Medicare ID for dual eligible individuals when feasible.**
- **That QHP issuers in FFEs use the Medicare ID for their enrollees in the administration of their plans.**

AHIMA believes that all policy avenues should be pursued in seeking to improve patient identification to facilitate improved patient safety, better care coordination and advance interoperability. However, we recognize that Medicaid and CHIP churning presents challenges in the adoption of a CMS-wide identifier.<sup>14</sup> For that reason, we recommend at a minimum, that CMS pilot an agency-wide identifier to evaluate its effectiveness in the programs cited above. We also recommend that CMS publicly release the findings of the pilot study. Such transparency will help advance private-sector led initiatives in the development of a coordinated national strategy to enhance patient identification.

**(4) Should CMS advance more standardized data element across all appropriate programs for matching purposes, perhaps leveraging the USCI proposed by ONC for HHS adoption ay 45 CFR 170.213?**

AHIMA recommends that CMS work with ONC to require, as part of the US Core Data for Interoperability (USCDI), the use of well-tested standards for certain demographic data elements to improve patient matching rates. More specifically, we recommend that ONC specify the use of the US Postal Service standard for “address” under the USCDI. A recent study indicates that use of the US Postal Service standard could improve match rates by 2-3 percent.<sup>15</sup> Evidence suggests that further standardization of “last name” and “address” could improve the match rate further by as much as 8 percent.<sup>16</sup> To further validate the use of this standard, CMS could collaborate with USPS to pilot the use of the postal service’s API-based tool across appropriate CMS programs. CMS should also consider use of the US Postal Service standard as a potential improvement activity under the Patient Safety and Practice Assessment subcategory within the MIPS Improvement Activities performance category under the Quality Payment Program.

AHIMA also recommends that CMS work with ONC, industry and experts to identify other regularly

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<sup>14</sup> Available at: [https://www.commonwealthfund.org/publications/journal-article/2016/oct/insurance-churning-rates-low-income-adults-under-health?redirect\\_source=/publications/in-the-literature/2016/oct/insurance-churning-low-income-adults](https://www.commonwealthfund.org/publications/journal-article/2016/oct/insurance-churning-rates-low-income-adults-under-health?redirect_source=/publications/in-the-literature/2016/oct/insurance-churning-low-income-adults).

<sup>15</sup> Grannis, Shaun J, Xu, Huiping, et al. “Evaluating the effect of data standardization and validation on patient matching accuracy.” *Journal of American Medical Informatics Association*, 2019; 5 (26): 447-456  
<https://doi.org/10.1093/jamia/ocy191>

<sup>16</sup> Id.

collected demographic data elements that could be incorporated into the USCDI to improve patient matching. For example, the availability of an email address in a patient's record has increased over time from 8.94 percent in 2005 to 54.08 percent in 2014.<sup>17</sup> Email addresses could serve as another critical datapoint in accurately matching a patient to their health information.

**(7) To what extent should patient-generated data complement the patient-matching efforts?**

Patient-generated data, including biometrics offer tremendous potential in improving patient matching rates when accompanied by established data governance policies and procedures as well as ongoing data quality improvement efforts. A recent study from the Pew Charitable Trusts demonstrated that in one hospital more than 90 percent of patients agreed to use a biometric system for identification.<sup>18</sup> That said, the collection and use of biometric information can also invite privacy and security risks with respect to state and federal privacy laws.<sup>19</sup> The cost of implementation and maintenance of biometric technologies can also be an important consideration in the adoption of such technologies by clinicians.<sup>20</sup> We recommend that should CMS require the adoption or use of patient-generated data technologies across its programs, that it take into account these important considerations. We also recommend that CMS require the adoption and use of foundational data governance and data quality improvement policies and procedures to improving overall data integrity.

We appreciate the opportunity to submit comments on the Medicare and Medicaid Program; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in Federally-facilitated Exchanges and Health Care Providers proposed rule. We hope that you will continue to engage extensively with stakeholders on the proposed rule and we look forward to working with you to ensure its successful finalization and implementation. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Senior Director, Federal Relations, at [lauren.riplinger@ahima.org](mailto:lauren.riplinger@ahima.org) and (202) 839-1218.

Sincerely,



Dr. Wylecia Wiggs Harris, PhD, CAE  
Chief Executive Officer  
AHIMA

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<sup>17</sup> Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6241737/>.

<sup>18</sup> "Enhanced Patient Matching is Critical to Achieving Full Promise of Digital Health Records." Pew Charitable Trusts, October 2018. Available at: <https://www.pewtrusts.org/en/research-and-analysis/reports/2018/10/02/enhanced-patient-matching-critical-to-achieving-full-promise-of-digital-health-records>.

<sup>19</sup> Hedges, Ron. "Privacy and Security Risks with Biometrics" *Journal of AHIMA* 89, no.8 (September 2018): 46-47. <http://bok.ahima.org/doc?oid=302573#.XL4cl1VKhEY>.

<sup>20</sup> Id.