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Mary Rasenberger Policy Advisor for Special Programs U.S. Copyright Office James Madison Memorial Building Room LM-401 101 Independence Ave., S.E. Washington, D.C. 20559-6000

Sent via e-mail: section 108@loc.gov

Dear Ms. Rasenberger:

MLA, a nonprofit, educational organization, comprises health sciences information professionals with more than 4,500 members worldwide. Through its programs and services, MLA provides lifelong educational opportunities, supports a knowledgebase of health information research, and works with a global network of partners to promote the importance of quality information for improved health to the health care community and the public.

Specific responses to questions raised by the Working Group include:

Are there conditions under which electronic access to digital preservation or replacement copies should be permitted under subsections 108(b) or (c) outside the premises of libraries or archives (e.g., via e-mail or the Internet or lending of a CD or DVD)? If so, what conditions or restrictions should apply?

MLA believes there are conditions under which electronic access to digital preservation or replacement copies should be permitted under subsections 108(b) or (c) outside the premises of libraries or archives.

With regard to the library's role in education, the physical setting of the health sciences library is no longer the exclusive center of a student's universe of independent learning, and the health profession school in which the student is enrolled is no longer the exclusive domain of the learner's universe. Many hospitals and health centers, companies, professional associations, and healthcare organizations have also heavily invested in distance medical education.

Additionally, the World Wide Web has become an ever-more important information resource and was designed to be shared outside the premises of libraries or archives. There has been growing interest in preserving parts of it, especially as clinical care and healthcare research becomes more global in nature.

Increasingly, healthcare organizations are generating tremendous amounts of electronic information that often resides on institutional servers, databases and silos. Libraries are

increasingly being asked to develop institutional repositories that preserve this information. Further, regulatory compliance laws such as HIPAA and Sarbanes-Oxley may mandate the retention of this information. Much of this information, however, is created or distributed through vendors with which client businesses have license agreements.

Additionally, as we have observed through recent catastrophic disasters such as 9/11 and Katrina, electronic access to digital preservation or replacement copies containing health information is vital to sustaining the health of the nation not only in immediately responding to disasters but also in assisting with the long term recovery associated with disasters.

Should any permitted off-site access be restricted to a library's or archives' "user community"? Yes.

How would this community be defined for the different types of libraries? The medical community is fairly well defined and includes students, researchers, faculty, staff, and medical personnel connected to the institution in which they serve. These groups of learners may also be defined as: 1) corporate learners who work for the organization and are seeking to maintain and upgrade skills, or complete degrees; 2) adult learners who are working to complete degrees; and 3) remediation and test preparation learners who are focused on learning as a prerequisite to an examination or certification or approval by accrediting organizations

To serve as an effective limit, should it represent an existing and well-defined group of users of the physical premises, rather than a potential user group (e.g., anyone who pays a member fee)? In the health professions, the need for access to health information, be it for education, research, or patient care, takes place both on and off the physical premises of the institution. Limiting access to an existing and well-defined group of users of the physical premises is not recommended as in today's environment, it is often the case that even users located in the same medical center complex where the library is physically located may rarely visit the library. With the increasing globalization of medicine, clinical care, research and education programs often include a defined community who many never physically visit the library. Distance education programs for the health professions are frequently offered to communities of users who never use the physical library facilities. Research teams are composed of experts in many countries and the diagnosis and/or treatment of diseases can involve experts from international medical centers.

Should off-site electronic access only be available where a limited and well-defined user community can be shown to exist? Generally, the answer to this question is yes. However, it should be recognized that the defined user group is often fluid. Increasingly, there is a need for just-in-time learning for groups of researchers or clinical care givers that come together for limited time periods with a specific focus. Also, given the critical nature of health information during emergencies or disasters, it may be wise to build in some type of "safe harbor" that would allow access to less well-defined user communities.

Should restricting remote access to a limited number of simultaneous users be required for any off-site use? There are at least three major difficulties with this approach to limiting access: 1) in today's technological world controlling all the variables for which there are values that can satisfy all the equations that define simultaneous use is impossible; 2) technology is neutral and can be used or abused according to user needs/expectations and will thus find a way around any such artificial restriction; 3) this approach assumes that we know the technology of the future and how it will work, which we don't.

Would this provide an effective means of controlling off-site use of digital content so that the use parallels that of analog media? This question assumes that digital will be the format of the future and that content transmission should parallel that of analog media. Either assumption is questionable.

If a limit on simultaneous users is required for off-site access to unlicensed material, what should that number be? The answer to this question depends on many factors and there is probably no one correct number.

Should only one user be permitted at a time for each legally acquired copy? No. See above example.

Do effective technologies exist to enforce such limits? Most authentication systems require some form of electronic user registration and subsequent access control and monitoring. The concept of username (identifier) and password (authenticator) in computing is as widespread as the use of the library card in libraries; however, it is seldom used in Internet information services. Additionally, there are several problems of scale and detail in registering and securing access on a public network, Technologies do exist and are improving with each new version. Various technical measures help protect against accidental and deliberate breaches of the economic, quality, and confidentiality interests of provider and user alike, but their effectiveness varies a great deal from situation to situation. At present, much improvement is needed; application of these technologies often creates unnecessary barriers for those who need to access information at critical times, and the use of these technologies frequently impose additional costs not easily absorbed by institutions with narrow operating margins.

Should the use of technological access controls by libraries and archives be required in connection with any off-site access to such materials? Yes, where it can be demonstrated that the technological access controls are effective, do not impose unnecessary and unreasonable barriers to access and/or promote the widening of the digital divide between the haves and the have nots.

Do the relevant provisions of the TEACH Act provide a good model? NO. The provisions of the TEACH Act that have relevancy are those that are meant to limit the kinds of material that can be used and those that attempt to define eligible institutions (nonprofit accredited educational institution or a governmental agency). How content is used rather than format control should be the focus of any copyright revisions. Further, attempting to define libraries by attributes such as profit/non-profit or accredited or non-accredited is not necessary and like simultaneous use has too many variables to control for.

Would it be effective to also require library and archive patrons desiring off-site access to sign or otherwise assent to user agreements prohibiting downloading, copying and downstream transmission? It is doubtful that this approach would be effective. Using Section 108 brings with it a certain level of responsibility. In exchange for receiving a pretty extraordinary exemption, libraries and their employees are responsible for making sure the statute is not abused. However, users concede that they make copies despite the potential legal liability to them and the library. As a practical matter, this approach is much like "clickable" licenses or "shrink wrap" licenses that many states have ruled as unenforceable and/or illegal.

Should the rules be different depending on whether the replacement or preservation copy is a digital tangible copy or intangible electronic copy (e.g., a CD versus an MP3 file) or if the copies originally acquired by the library or archive were acquired in analog, tangible or

intangible digital formats? No. Again, this question focuses on attempting to control access by controlling the information container rather than the use of the content itself. This approach to access control is short-sighted as information containers are certain to change. Whatever rights and/or privileges were present when the original was purchased should follow with the surrogate copy, whatever the format the surrogate copy uses, rather than trying to impose a new set of rights and privileges just because the information container has changed.

Since the roles and responsibilities of libraries for providing public access have not changed simply because the format of material has moved from analog to digital, it is reasonable to assume that the rights to perform these societal tasks have not significantly changed either. Leveraging the existing system of library and archives, with its existing approaches to serving users, can be easily extended to include providing public access to material in digital containers or any other future information container. Leaders in libraries, archives, and public policy groups can have and should be allowed to have a far-reaching impact on the future of healthcare, research, education and scholarship by offering universal access to our cultural heritage regardless of the container in which that heritage is housed.

MLA also offers the following comments on the general issues raised by the Working Group concerning eligibility and making copies for replacement and preservation purposes.

Eligibility for Section 108 Exceptions. Eligibility for section 108 should be based on the institution's activities, which fall into the non-profit domain, rather than whether they are a forprofit or non-profit entity. Within the broad biomedical and health sciences arena, there are numerous for-profit institutions that provide a social good through educational and community activities that have no direct or indirect commercial advantage. For example, a for-profit hospital may have a library that provides health care information to consumers in the community. The entity is for-profit, but the purpose is non-commercial and non-profit. These groups should be allowed to take advantage of section 108 provisions.

The definition should be expanded beyond physical libraries and archives. At the very least museums should be included because they have missions and activities that are very closely aligned and overlapping with libraries and archives. Given the changing world, virtual libraries, archives, and other entities may become more and more predominant. While virtual institutions should be included, they should be held to the standard of being available to the public, even if it is merely through Internet connections and not traveling to a physical location.

Libraries and archives are turning to outsourcing as a cost-effective and efficient method for operations, especially for digital preservation and copying services. However, the outsourcing should be done on behalf of the library or archive that meet the eligibility criteria. The activities should NOT provide any commercial advantage to the organization providing the outsourcing services.

Certification or credentialing of eligible libraries, archives and other entities should NOT be implemented. Such a system would essentially create a barrier, especially for smaller institutions, to utilize the privileges granted them in section 108.

Making Copies for Preservation and Replacement Purposes. This section needs to focus on the access to and distribution of copies and not on the number of copies being made. Given digital technology, the number of copies is becoming a difficult and obsolete concept. However, in the digital world it is very easy to set up systems that restrict access and distribution.

Preservation can no longer wait for the deterioration or loss of a work. Up-front preservation should be allowed, since once digital material deteriorates or is damaged in any way all data can be lost.

In addition, the concepts of "unstable" or "fragile" should be added to the other criteria for making a copy of both digital and analog materials. The lifetime of new digital media such as CD-ROMs has come under question and copies need to be made to ensure continued access beyond the life expectancy of the specific media.

"Obsolete" should not just refer to the format any longer. Digital materials also run the risk of becoming obsolete in terms of the version of the software or systems platform that may support the work. Some changes no longer support older file types or software versions. Preservation should also allow for migration of materials to newer versions, especially when the author/producer is no longer upgrading the software or files. In addition to copies, libraries and archives should be to save word-processing, PDF and other file types using newer versions of application software so that the materials are available in the future.

The points above also lead to the conclusion that "preservation-only" copies of works should be allowed upon acquisition. However, there should be no access allowed to the "preservation copy". The purchase order, invoice, or license agreement could be used as the legal document that indicates the number of original copies that were purchased and that would be the maximum number of preservation copies that could be held at any given time. Preservation copies should not be accessible to users. The copies should be maintained in a restricted archive and never circulated unless the original is lost or damaged.

The right to make copies should NOT be limited to those institutions that meet certain criteria. All institutions that are eligible should have the right to preserve and protect works that they have purchased and which are at risk of damage or loss of data.

Eligible institutions should also be allowed to circumvent protection measures that prevent copying for preservation or replacement purposes as defined elsewhere in section 108.

These sections should apply to both analog and digital materials that are at risk of near-term deterioration.

We hope that these comments are helpful to the Working Group as you consider recommendations for possible amendments to section 108 exceptions and limitations. If we can provide additional information, please let us know.

Sincerely,

Carla J. Funk, CAE Executive Director

Carla J. Funk