BEFORE THE CITY COUNCIL

OF THE CITY OF LAS VEGAS, NEVADA

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IN THE MATTER OF:

DEPARTMENT OF FINANCE AND BUSINESS SERVICES on behalf of the CITY OF LAS VEGAS, NEVADA,

Petitioner,

vs.

GASTROENTEROLOGY CENTER OF NEVADA, and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC,

Respondents.

COMPLAINT FOR DISCIPLINARY ACTION

The DEPARTMENT OF FINANCE AND BUSINESS SERVICES, on behalf of the CITY OF LAS VEGAS, NEVADA (Department), Petitioner, brings this Complaint for Disciplinary Action against GASTROENTEROLOGY CENTER OF NEVADA, 700 Shadow Lane, Las Vegas, Clark County, Nevada, and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC, 700 Shadow Lane, Las Vegas, Clark County, Nevada, Respondents, and states:

1. Respondent GASTROENTEROLOGY CENTER OF NEVADA, holds Medical Clinic License No. C14-00266-6-091934, and Respondent ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC, held Medical Clinic License No. C14-00367-3-107022.

2. ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC formerly held Medical Clinic License No. C14-00367-3-107022. The owners are listed as Dipak Desai, M.D., Vishvinder Sharma, M.D., Eladio Carrera, M.D., and Clifford Carrol, M.D. That license was allowed to lapse for nonpayment of business license fees November 15, 2007. On

February 29, 2008, an agent of the licensee tendered the business license fees owed, and an agent of the Financial Services Division accepted the monies.

On February 5, 2002, Dipak Desai, M.D., Eladio Carrera, M.D. and Vishvinder Sharma, M.D. applied for a medical clinic license for GASTROENTEROLOGY CENTER OF NEVADA located at 700 Shadow Lane, Las Vegas, Nevada. Medical Clinic License No. C14-00266-6-091934 was issued to them.

3. On February 29, 2008, Jim DiFiore, Manager, Business Services Division, Department of Finance and Business Services, City of Las Vegas, caused an immediate emergency suspension of City business licensure including but not limited to Medical Clinic License No. C14-00266-6-091934 to be served on GASTROENTEROLOGY CENTER OF NEVADA f/k/a ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC at 700 Shadow Lane, Las Vegas, Clark County, Nevada. His decision was upheld following a prompt post-suspension administrative hearing March 3, 2008.

SUMMARY OF ALLEGATIONS

4. Recently, a composite team of investigators from the Southern Nevada Health District, the Nevada Bureau of Licensure and Certification, and the federal Centers for Disease Control and Prevention investigated GASTROENTEROLOGY CENTER OF NEVADA and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC. They determined that between March 2004 and continuing through January 11, 2008[1], at least 40,000 procedures were performed on patients utilizing techniques that fell well below accepted medical practice. Registered nurses and certified registered nurse anesthetists were directed by administrators to reuse syringes when administering anesthesia. In addition, they were instructed to then reuse vials of medication. This resulted in cross contamination between patients.

5. The Bureau of Licensure and Certification made findings that the Code of Federal Regulations was violated by GASTROENTEROLOGY CENTER OF NEVADA and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC. Specifically, 42 C.F.R. § 416.41

[1] This represents 1,412 days.

(dealing with ambulatory surgical centers) and 42 C.F.R. § 416.48 (also dealing with ambulatory surgical centers) were violated. Management did not "assure that . . . services [were] provided in a safe and effective manner." GASTROENTEROLOGY CENTER OF NEVADA and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC did not "provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice."

6. The Southern Nevada Health District, as a result of its participation in the investigation, found that it was a mandated practice at GASTROENTEROLOGY CENTER OF NEVADA and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC to use a clean syringe and needle to draw a sedative[2] from a new single-use vial when sedating an endoscopy patient. The sedative was then administered to the patient. This administration resulted in the possibility of back flow of blood, from the patient, into the syringe. The needle on the syringe was then replaced, but the original, contaminated syringe was sometimes reused to draw additional sedative from the same vial for the same patient. This created the possibility of contaminating the vial with diseased biological material from the first patient. GASTROENTEROLOGY CENTER OF NEVADA and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC would then use a clean needle and syringe while administering sedation to a second patient. However, the sedative was sometimes drawn from the original, single-use, potentially contaminated vial. This put subsequent patients at risk for infection.[3] Investigators initially determined that, as a result of this dangerous practice, a patient was infected with Hepatitis C in July 2007 and five other patients were infected with Hepatitis C in September

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[2] The sedative in use was Propofol a/k/a Diprivan. It is marketed by AstraZeneca International. The AstraZeneca International website provides instructions for the use of Propofol, including "Additional Precautions." AstraZeneca International writes, "DIPRIVAN contains no antimicrobial preservatives and supports growth of micro-organisms." The warning is given that "**[w]hen DIPRIVAN is to be aspirated, it must be drawn aseptically into a sterile syringe** or giving set immediately after opening the ampoule or breaking the vial seal. Administration must commence without delay. Asepsis must be maintained for both DIPRIVAN and infusion equipment throughout the infusion period. . . . **DIPRIVAN and any syringe containing DIPRIVAN are for single use in an individual patient**. [Emphasis added.]"

[3] Please see Exhibit 1, a copy of an illustration entitled "Unsafe Injection Practices and Disease Transmission" found on the Southern Nevada Health District website.

2007. At least 40,000 other patients were put at risk of infection with life-threatening communicable diseases.

7. Investigators also determined that, as a matter of mandated practice, employees of GASTROENTEROLOGY CENTER OF NEVADA and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC would reuse the same cleaning solution when sterilizing endoscopes used for procedures on different patients.

SUBSTANTIVE LAW

8. LVMC § 6.02.330(H) provides:

> The licensee may be subject to disciplinary action by the City Council for good cause, which may, without limitation, include:
>
> . . . .
>
> **The actual business activity** constitutes a public or private nuisance, or **has been or is being conducted in an unlawful, illegal or impermissible manner**. [Emphasis added.]

9. LVMC § 6.02.350 provides:

> A licensee under this Chapter shall be subject to disciplinary action not only for acts or omissions done by such licensee but also for acts and omissions done by the **principals, managers**, agents, representatives, servants or **employees** of such licensee. [Emphasis added.]

10. 42 C.F.R. § 416.41 provides:

> The ASC [ambulatory surgical center] must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for **ensuring that these policies are administered so as to provide quality health care in a safe environment**. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. Standard: Hospitalization. The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital. [Emphasis added.]

. . . .

11. 42 C.F.R. § 416.48 provides:

> **The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice**, and under the direction of an individual designated responsible for pharmaceutical services.
>
> (a) Standard: Administration of drugs. **Drugs must be prepared and administered according to established policies and acceptable standards of practice.**
>
> (1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.
>
> (2) Blood and blood products must be administered by only physicians or registered nurses.
>
> (3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician. [Emphasis added.]

EVIDENCE

12. LVMC § 6.88.090 provides:

> (A) The hearing need not be conducted according to technical rules relating to evidence and witnesses. Any relevant evidence may be admitted.
>
> (B) The respondent shall have the right to call and examine witnesses on his own behalf, cross-examine opposing witnesses, introduce exhibits and evidence relevant to the issues of the case, and offer rebuttal evidence.
>
> (C) The respondent may be called and examined by the City.
>
> (D) The Clerk shall have the power to issue subpoenas for witnesses to appear to give testimony.

PENALTY

13. LVMC § 6.02.360 provides:

> Upon a showing of good cause and in the discretion of the City Council, disciplinary action against a holder may take the form of **cancellation**, **revocation**, refusal to renew, **suspension**, imposition of conditions or restrictions or civil **fine** in an amount not to exceed one thousand dollars for each day that the violation which forms the subject matter of the complaint that recommends such disciplinary action is demonstrated to have been in existence, or any combination of such actions, as the particular situation may require. The Council may also impose against the

licensee the actual costs incurred, and a reasonable amount for attorney's fees, resulting from the imposition of disciplinary action. The disciplinary actions available in this Section shall be in addition to, and not exclusive of, any other civil or criminal remedy which otherwise might be available. [Emphasis added.]

ALLEGATION

It is alleged that between March 2004 and January 11, 2008, GASTROENTEROLOGY CENTER OF NEVADA and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC's actual business activity constituted a public nuisance, and was conducted in an unlawful, illegal and impermissible manner. GASTROENTEROLOGY CENTER OF NEVADA and ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC put at least 40,000 patients at risk of infection with life threatening, communicable diseases, including, but not limited to, Hepatitis C, Hepatitis B, and Human Immunodeficiency Virus (H.I.V.). The techniques described herein fell well below accepted medical practice. These techniques were practiced intentionally, as a result of administrative direction, and were not the result of inadvertence. Policymaking agents of the licensees, until caught, chose to mortally hazard patients for profit.

WHEREFORE, the Petitioner respectfully requests the City Council to:

A. Approve the Complaint for Disciplinary Action and order a disciplinary hearing at which the Respondents shall appear and show cause why the licenses that are the subject of this Complaint should not be suspended or revoked, or other disciplinary action taken; or

B. Grant such other and further relief as the Council deems appropriate.

DATED this 18 day of March, 2008.

RESPECTFULLY SUBMITTED:

By: _____
MARK R. VINCENT, Director
Finance and Business Services

BRADFORD R. JERBIC
City Attorney

By: _____
WILLIAM P. HENRY
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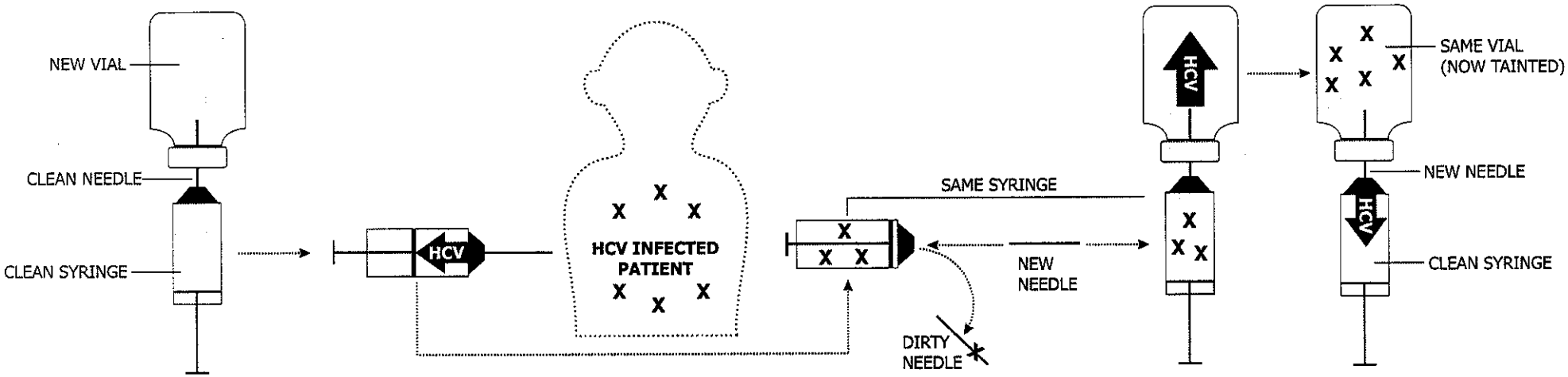
Las Vegas, NV 89101
Attorneys for CITY OF LAS VEGAS

EXHIBIT 1

Unsafe Injection Practices and Disease Transmission

Reuse of syringes combined with the use of single-dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.



1. A clean syringe and needle are used to draw the sedative from a new vial.

2. It is then administered to a patient who has been previously infected with hepatitis C virus (HCV). Backflow into the syringe contaminates the syringe with HCV.

3. The needle is replaced, but the syringe is reused to draw additional sedative from the same vial for the same patient, contaminating the vial with HCV.

4. A clean needle and syringe are used for a second patient, but the contaminated vial is reused. Subsequent patients are now at risk for infection.