The Andhra Pradesh Informed Choice of Clinical Establishments Bill, 2017

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WHEREAS it is evidently imperative to improve transparency and information disclosure in the healthcare sector, and bridge the existing information asymmetry between the patients and clinical establishments so as to empower the patients to make informed healthcare choices, through the creation of a universally accessible, robust clinical establishments’ data registration-aggregation-access system;

AND WHEREAS it is necessary to engender an effective and independent monitoring and grievance redressal mechanism, under the supervision of credible healthcare professionals, to facilitate the institutional accountability of, sound decision-making by and adoption of best practices by the clinical establishments;

AND WHEREAS it is of utmost importance to restore and enhance public trust in healthcare providers and clinical establishments, through the above measures, while effectively reconciling quality of healthcare and cost of services;

AND WHEREAS the Legislature of the State is empowered to make laws with respect to the matter of 'public health and sanitation; hospitals and dispensaries' that comprises Item No. 6 of the LIST II – STATE LIST of the SEVENTH SCHEDULE, under the mandate of Article 246(2), PART – IX: Chapter I - Legislative Relations (Distribution of Legislative Powers) of the Constitution;

Be it enacted in the Sixty-eighth year of the Republic of India by the State Legislature of Andhra Pradesh as follows:—

CHAPTER I:
PRELIMINARY

1. Short title, extent and commencement.
(1) This Act maybe called The Andhra Pradesh Informed Choice of Clinical Establishments Act, 2017;

(2) It applies to the whole of the State of Andhra Pradesh;

(3) It shall come into force on such date as the State Government may, by notification in the Official Gazette, appoint.

2. Definitions.
In this Act, unless the context otherwise requires,—

(1) “Clinical establishment” means and includes,
(a) a hospital, nursing home, clinic, dispensary, maternity home, sanatorium, rehabilitation center or an institution by whatever name called, including those that have an attached pharmacy, that offers (or seeks to offer) or provides (or seeks to provide) services and facilities for medical, surgical, dental, radiological, physiotherapy, or diagnosis, treatment, care or other services;

(b) an establishment that provides (or seeks to provide) preventive, primary, secondary, or tertiary healthcare services to babies, children, pregnant women and adults;

(c) an establishment that provides (or seeks to provide) clinical care under allopathic or any or all other systems of medicine recognized by the Government of India, including Ayurveda, Unani, Siddha, Homeopathy, Naturopathy and Yoga (AYUSH); and

(d) a place established (or that seeks to be established) as an independent entity or as part of an establishment referred to in sub-clause (i)(a), and that provides services of the nature of inpatient care, diagnostic center or a laboratory, and shall include a clinical establishment owned, controlled or managed by –

(i) the government or a department of the Government;

(ii) a trust (including a foundation), whether public or private;

(iii) a corporation (including a society) registered under a Union or State Act, whether or not owned by the Government;

(iv) a local government;

(v) a group of doctors or private citizens,

and shall include a clinical establishment already established and/or functioning at the time of commencement of this Act,

but does not include a clinical establishment –

(a) owned, controlled or managed by a single doctor or care giver, exclusively for providing outpatient services (with or without basic diagnostics or laboratory testing), including physiotherapy, dental and AYUSH services;

(b) owned, controlled or managed by the Armed Forces;

(c) that solely provides mental health services covered under the Mental Health Act, 1987.

(2) “Diagnostic center” or “laboratory” means a place established as an independent entity or as
part of a clinical establishment in connection with the diagnosis and treatment of diseases, where biochemical, pathological, bacteriological, genetic, radiological investigations or other diagnostic or investigative services, with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not.

(3) “State Council” means the Independent State Council of Clinical Establishments established under the provisions of this Act for the entire State of Andhra Pradesh;

(4) “District Council” means an Independent Council of Clinical Establishments established under the provisions of this Act for a revenue district within the State;

(5) “City Council” means an Independent City Council of Clinical Establishments established under the provisions of this Act for a metropolitan city.

(6) “Registering authority” means the relevant Independent District Council or City Council of Clinical Establishments established under the provisions of this Act for the geographical area in which the clinical establishment operates.

CHAPTER II:
MANDATORY REGISTRATION, SELF-DISCLOSURE, TRANSPARENCY & REGISTERING AUTHORITY

3. Mandatory Registration and Registering Authority.
(1) Subject to the relevant provisions of this Act, it is mandatory for all clinical establishments, whether newly established or existing, to be either provisionally or permanently registered in the prescribed online manner with the Independent District or City Council, as the case may be, before they can operate or continue to operate.

(2) No clinical establishment shall be issued a permanent registration, without it obtaining a provisional registration first.

(3) A provisional registration shall be issued within ten days of submission of a valid online application, provided that it is ordinarily issued as a matter of right upon provision of satisfactorily complete and accurate information by the clinical establishment and fulfilment of minimum conditions for operation, unless the disclosure of information is insufficient; provided further that if the registering authority does not act within ten days, the provisional registration is deemed to have been granted to the clinical establishment.

(4) Permanent registration is deemed to have been issued one year from issue of provisional registration, unless specified otherwise by the registering authority.

(5) The council may shorten the process of permanent registration if the CE is already accredited by an independent, credible professional/certifying body.
(6) Clarifications may be sought by the registering authority, as is necessary, about the validity of the information furnished, and to carry out scrutiny, as necessary, based on information provided in public domain, or following comments or queries made by members of the general public.

(7) The State Council shall frame relevant bye-laws, requirements and guidelines governing the manner for processing of application, including the proforma for registration application and information disclosure, the manner of scrutiny, verification and validation of the information provided by a clinical establishment, as may be required.

(8) Once a permanent registration has been issued, the clinical establishment shall furnish information about any changes in status with respect to infrastructure, equipment, personnel, services provided and their prices.

(9) Non-compliance with any of the provisions, terms and conditions, etc. of application for registration would be deemed to be a violation of this Act and shall result in appropriate penalties to be imposed on the concerned clinical establishment.

(10) The Independent District or City Council, as the case may be, shall act as the concerned registering authority under this Act.

(11) The registering authority shall receive and process the registration application of a clinical establishment, towards provisional registration.

(12) Following the submission of a valid registration application and the disclosure of required information in the process and manner prescribed, the District or City Council shall issue provisional registration to the concerned clinical establishment, in a manner prescribed.

(13) The process, procedure and proforma(s) for provisional or permanent registration, as the case may be, shall be as prescribed by the State Council, and shall be simple, easy-to-comply and relevant.

(14) The provisional or permanent certificate of registration, as the case may be, as issued by the registering authority shall be prominently displayed by the clinical establishment for public viewing.


(1) The issue of provisional or permanent registration, as the case may be, is conditional upon the transparent and accurate disclosure of complete information by the clinical establishment, in the prescribed format and manner.

5. Disclosure of Information.

(1) By the clinical establishment – The information to be provided by a clinical establishment shall be prescribed by the State Council and shall include all relevant information such as –

   (a) Physical infrastructure and ancillary facilities;
(b) Clinical and healthcare equipment available, their relevant specification/details such as make, manufacturer, efficacy, etc., and shall include the duration of their functioning and utilization over a given time period;

(c) services provided at the clinical establishment;

(d) details of personnel whose services are being provided to patients at the clinical establishment - based on the nature of their service, role and responsibility - including their relevant professional qualifications, certifications, trainings, work experience, and details of all current professional engagements/employment of the personnel, including association with, or employment by, other clinical establishments;

(e) the rates/fees/prices charged by the clinical establishment for each of the services and amenities provided including preventive, diagnostic, laboratory and medical interventions, surgeries, other procedures; including, but not limited to, consultation fees, charges for support & ancillary services, housekeeping charges, room rent, and incidentals;

(f) whether the clinical establishment is in compliance (full or otherwise) with any law, rule, regulations, guidelines and such other, as may be applicable, in respect to healthcare services and tariffs charged;

(g) a meaningful and intelligible statistical compilation of clinical services and healthcare performance outcomes, including the number of procedures, interventions, laboratory tests, diagnostics surgeries performed, outpatient visits, mortality rates, morbidity rates and such other;

(h) overview of the governance mechanisms, systems and processes being practiced by the clinical establishment, such as details of internal & external audits, periodic reviews, mortality and morbidity reviews, committee meetings, board meetings and such other;

(i) accreditations received through credible national and international accreditation bodies such as National Accreditation Board for Hospitals and Healthcare Providers (NABH) and National Accreditation Board for Testing and Calibration Laboratories (NABL), and Joint Commission International (JCI), as may be provided for, by the State Council;

(j) compliance status with applicable regulations made by healthcare regulatory bodies, including the National e-Health Authority;

(k) compliance status with applicable laws, regulations, standards, codes, and others such as fire safety codes, radiation safety standards, and pollution standards, concerning buildings, premises, constructed spaces, installation and operation of equipment and disposal of biomedical waste;
any change in status with respect to infrastructure, equipment, services provided, personnel, or tariffs aforementioned, as disclosed by the clinical establishments at the time of registration, or updated subsequently, shall be communicated to the registering authority and also be made publicly available, in the prescribed manner, within fifteen days of change in status, provided that tariffs shall be upwardly revised only ten days following the date of submission of such information; and

(m) any other information as may be required by the State Council from time to time.

(2) By the registering authority and/or the State Council –

(a) the State Council, either separately or through the registering authority (i.e. Independent District or City Council, as the case may be), shall ensure that clinical establishments prominently display their individually-disclosed information, as in sub-section (1), within the premises of the clinical establishment, and/or make it easily available to the public, and ensure wide dissemination, especially through the use of modern technology as given in section 8;

(b) the State Council shall act as the statutory custodian of the information provided, collected and disclosed under this Act;

(c) the State Council, either separately or through the registering authority (i.e. Independent District or City Council, as the case may be), shall ensure that the aforementioned information is compiled, categorized, summarized, disseminated in an intelligible manner, and permanently codified and archived, especially by utilizing modern technology;

(d) the information aggregation is to be standardized so as to facilitate meaningful comparison and informed choice by consumers/the public;

(e) the State Council shall prescribe the information disclosure procedures, processes, proformas, norms, etc. for various categories of clinical establishments; and

(f) all clinical establishments shall mandatorily provide and publicly disclose information as required by the State Council in accordance with the provisions of this Act.

6. Use of information technology for most effective, efficient outcomes.
(1) The State Council shall ensure that the entire process of registration, disclosure of information, updating of any information, storage and dissemination of such matter pertaining thereto, shall be made accessible in the prescribed manner, either universally/publicly or otherwise, as the case may be.

(2) Maintain this information through a secure, robust and accessible information technology-based platform(s)/systems for most effective, overall outcomes and through the most efficient
use of resources, by utilizing the IT/ITES-based technology (including, but not limited to the internet/web, intranet, dedicated networks, mobile apps).

7. **Registration Application Processing and Annual Fees.**
   (1) The State Council may prescribe a reasonable application processing fee structure for clinical establishments seeking registration, either provisional or permanent, taking into account the nature of such the clinical establishment, local conditions, capital investment, services and nature of care provided such as family, secondary, or tertiary care, and such other relevant factors/criteria.

(2) The State Council may prescribe a reasonable annual fee structure for clinical establishments with existing registration, either provisional or permanent.

(3) The expenditure of the State Council and the Independent District and City Councils shall be charged to the consolidated fund of Andhra Pradesh as per provisions under Article 202(3)(f) of the Constitution.

**CHAPTER III: INDEPENDENT DISTRICT, CITY AND STATE COUNCILS**

8. **Independent District or City Council for Clinical Establishments.**
   (1) An Independent District or City Council for Clinical Establishments shall be the main monitoring authority for clinical establishments in the district or metropolitan city, respectively.

(2) Initially, the seven-member Independent District or City Council shall be constituted by the State Council as per the advice of a Search Committee composed of the District Medical & Health Officer; representatives of the district or city chapters of Indian Medical Association, Andhra Pradesh Nursing Homes Association and eminent civilians with credibility and history of good service nominated by the other members of the Search Committee with unanimous consent. The Search Committee is responsible for identifying the members of the Independent District or City Council.

(3) Subsequent selection of members shall be by cooption carried out by existing members of the Independent District or City Council, based on the creation of casual vacancies.

(4) Selection of members shall be through common consent of the Search Committee or the members of the Independent District or City Council. Dissent on valid grounds, even by a minority, should be respected in the selection process for new members.

(5) **Composition –**

   (a) An Independent District or City Council for Clinical Establishments shall be the main monitoring authority for clinical establishments in the district or metropolitan city, respectively. The seven-member body shall be composed of:
(i) one District Medical & Health Officer, *ex officio*; who shall be the Member Secretary;

(ii) three eminent medical practitioners of unimpeachable integrity, with common consent; of whom at least one shall be a trained diagnostic specialist with experience managing a diagnostic center/laboratory;

(iii) one eminent medical practitioner following one of the AYUSH systems of medicine; and of unimpeachable integrity, with common consent;

(iv) two reputed members representing state-level consumer groups or reputed non-governmental organizations working in the field of health in the district or city (or reputed social worker); through common consent.

(b) Of the seven-member body, a minimum of two members shall be women, and as such, shall also comply with the other criteria of composition.

(c) The Chairperson of the Independent District or City Council shall be chosen by the Council members from among themselves.

(d) Council members shall hold office for a term of three years, but shall be eligible for reappointment for a maximum of one more term of three years.

(e) A person shall be disqualified from being appointed as a member, or during their term, of being a member of the Independent District or City Council if he/she –

(i) has been convicted and sentenced to imprisonment for an offense which, in the opinion of the State Council, involves moral turpitude; or

(ii) is an undischarged insolvent; or

(iii) is of unsound mind and stands so declared by a competent court; or

(iv) has been removed or dismissed from the services of the Government or a Corporation owned or controlled by the Government; or

(v) is facing serious and credible accusations of abuse of office, moral turpitude, conduct unworthy of public trust, malafide discharge of duties or corruption, backed by *prima facie* evidence.

(6) The District or City Council shall meet at least once a month.

(7) *Functions* – The District Council for Clinical Establishments shall –
(a) Receive and process applications for provisional registration of clinical establishments in the district;

(b) issue registration certificates to clinical establishments;

(c) establish and maintain an online register of clinical establishments and the information disclosed by each establishment;

(d) mandate the display of rates at a prominent place in the clinical establishment, either in English or the local language, for all common services (including diagnostic and therapeutic) provided at the clinical establishment; excluding emergency services;

(e) upon credible complaint or suo moto, two representatives of the district council shall carry out an inspection of the respective clinical establishments to verify violations related to registration status, disclosed information, or institutional adherence to guidelines;

(f) function as the first redressal authority in the event of violation of this Act by clinical establishments and hold them accountable for the violation.


(1) There shall be an Independent State Council for Clinical Establishments to monitor the functioning District or City Councils, while also establishing guidelines for Clinical Establishments.

(2) Initially, the nine-member Independent State Council shall be constituted by the state government as per the advice of a Search Committee composed of the Vice-Chancellor of the NTR University of Health Sciences; Director, Medical Education; Director, Department of Health, Medical & Family Welfare; representatives of the Medical Council of India state chapter, Indian Medical Association state chapter, Andhra Pradesh Nursing Homes Association state chapter and eminent civilians with credibility and history of good service nominated by the other members of the Search Committee with unanimous consent. The Search Committee is responsible for identifying the members of the State Council.

(3) Subsequent selection of members shall be by cooption carried out by existing members of the Independent State Council, based on the creation of casual vacancies.

(4) Selection of members shall be through common consent of the Search Committee, or the members of the State Council as may be applicable. Dissent on valid grounds, even by a minority, should be respected in the selection process for new members.

(5) Composition –

(a) The State Council shall be composed of:
(i) the State Director, Medical Education, *ex officio*; who shall be the Member Secretary;

(ii) five eminent medical practitioners of unimpeachable integrity, selected with the common consent; of the Search Committee referred to in section; of whom at least one shall be a trained diagnostic specialist with experience managing a diagnostic center/laboratory;

(iii) one eminent medical practitioner following one of the AYUSH systems of medicine; and of unimpeachable integrity, with common consent;

(iv) two reputed members representing state-level consumer groups or reputed non-governmental organizations working in the field of health, with common consent (or credible social worker).

(b) Of the nine-member body, a minimum of two members shall be women, and as such, shall also comply with the other criteria of composition.

(c) The Chairperson of the State Council shall be chosen by the Council members from among themselves.

(d) The members shall hold office for a term of three years, but shall be eligible for reappointment for a maximum of one more consecutive term of three years.

(e) A person shall be disqualified for being appointed as a member, or during their term, of being a member of the State Council if he–

(i) has been convicted and sentenced to imprisonment for an offense which, in the opinion of the State Council, involves moral turpitude; or

(ii) is an undischarged insolvent; or

(iii) is of unsound mind and stands so declared by a competent court; or

(iv) has been removed or dismissed from the services of the Government or a Corporation owned or controlled by the Government; or

(v) is facing serious and credible accusations of abuse of office, moral turpitude, conduct unworthy of public trust, malafide discharge of duties or corruption, backed by *prima facie* evidence.

(6) The State Council shall meet at least once in three months.

(7) The State Council may make bye-laws, including for fixing a quorum, and for regulating its own procedures and the conduct of all business to be transacted by it.
(8) A separate Head of the Account shall be created to manage the funds available to the Independent State Council, including the amount earmarked from the annual budget for health services and the fees collected from the clinical establishments, so as to cover the administrative costs for the purpose of implementation of this law.

(9) **Functions** - The State Council for Clinical Establishments shall –

(a) establish and regularly update the State Register of clinical establishments and the information disclosed by them;

(b) act as the state-level appellate body for appeals of decisions of District or City Councils;

(c) determine categories of clinical establishments, the information to be disclosed by them and institutional guidelines for them to follow;

(d) establish a procedure for display of rates at a prominent place in the clinical establishment, either in English or the local language, for all common services (including diagnostic and therapeutic) provided at the clinical establishment; excluding emergency services;

(e) design updated institutional guidelines and clinical management guidelines under the guidance of the State Council to inform practitioners and patients, with due regard for quality and cost of services;

(f) monitor and compare performance indicators of clinical establishments identified by the State Council with states in India, other countries and with international standards, which may include the success and failure rates of key clinical procedures or surgeries, recovery rates, as decided by the State Council;

(g) disseminate guidelines and performance of clinical establishments through web-based and print media;

(h) publish an annual report on the state of implementation of standards within the state;

(i) update guidelines published by the State Council on a regular basis; and

(j) leverage on existing information technologies to provide appropriate information to the general public.

(10) **Power to seek advice or assistance**

The State Council retains the power to seek advice or assistance from professional bodies in the due course of carrying out its functions, such as establishing institutional and clinical management guidelines and selection of performance indicators for clinical establishments.

(11) **To follow consultative process**
The State Council may choose to seek external council as necessitated by the occasion.

(12) **Power to form bye-laws**
The State Council shall have the powers to frame bye-laws in the due course of carrying out its functions, or to maintain transparency of clinical establishments as required.

10. **Register of Clinical Establishments.**
(1) A web-based register of all registered clinical establishments is to be established and maintained by the State Council. District Councils and City Councils will maintain district-level and city-level registers which will be consolidated by the State Council.

(2) The state register of clinical establishments shall be displayed on a public domain; and shall contain all the self-disclosed information regarding clinical establishments to empower patients to make informed choices regarding healthcare providers.

(3) The state register shall be updated every three months.

11. **Design of Guidelines and Performance Monitoring.**
(1) The State Council is authorized under this Act to establish a permanent performance monitoring and research wing to carry out specific functions of the State Council as listed below—

   (a) design, publish and regularly update institutional guidelines under the guidance of the State Council to inform practitioners and patients about sound institutional practices; including maintenance of patient records, radiation safety measures, biomedical waste management, display of cost of services at the clinical establishment;

   (b) design and publish clinical management guidelines on appropriate care for common ailments, ailments for which over-diagnosis and over-treatment is prevalent, or those deemed necessary by the State Council; which shall be informed by national or international standards and evidence, with due regard to considerations of quality and cost of care; and shall be published in a staggered manner and updated as necessary;

   (c) monitor performance indicators of clinical establishments as identified by the State Council; compare them with other care givers, other states in India, other countries and with international standards;

   (d) publish an annual state-level report comparing cost of services and performance of clinical establishments, and the implementation of guidelines;

   (e) ensure dissemination of institutional guidelines, clinical management guidelines, and performance of clinical establishments to the general public through web-based and print media.

(2) The guidelines published by the State Council are intended to inform healthcare providers and patients, and serve as guidelines for patient care and healthcare institutional practices. In
individual cases, healthcare providers are free to exercise clinical judgment regarding patient care. However, institutional non-adherence to guidelines constitutes a violation of the provision of this Act.

12. Redressal Mechanism.
(1) The redressal mechanism under this Act shall specifically address institutional non-compliance to the provisions of this Act and the guidelines set by the State Council.

(2) Violations of provisions of this Act include –

(a) Non-registration of clinical establishment;

(b) Non-disclosure of information of clinical establishment;

(c) Non-payment by clinical establishment of application fee or annual fee;

(d) False disclosure of information of clinical establishment;

(e) Failure to update information of clinical establishments in a timely manner;

(f) Institutional non-adherence to guidelines;

(g) and any other institutional practices as deemed inappropriate or unethical by the State Council; including unnecessary or excessive use of diagnostic services unrelated to the disease, excessive billing, needless procedures, and partaking in unethical commissions for referrals or prescriptions, including denial of cashless treatment to which the patient is entitled under a health insurance policy.

(3) Individual cases of non-adherence to guidelines and cases of individual medical malpractice and/or negligence by healthcare professionals shall continue to follow existing redressal mechanisms under consumer protection laws and the Medical Council of India.

(4) Upon credible complaint or *suo moto*, the redressal authority is authorized to request the clinical establishment in question to furnish records for scrutiny.

(5) In case of non-registration, non-disclosure, falsification of information, deficiency or differences between the disclosed and available services, the District Council is to notify the establishment of the same. The clinical establishment will then have a period of one month to rectify the deficiencies and furnish information of the same to the authority.

(6) In the event of gross deviation from prescribed guidelines resulting in egregious harm to patient or patients, the clinical establishment will then have one month to explain their practices and rectify their deficiencies, failing which the District Council shall issue an appropriate penalty against the clinical establishment as decided by the District or City Council.
(7) Authorized Body –
(a) the District or City Council shall act as the first redressal body for violations by clinical establishments under this Act; which after due process, is authorized under this Act to issue penalties against the clinical establishment as appropriate;

(b) appeals regarding the decision of District or City Councils can be made with the State Council, which shall hold hearings to examine the appeal either as a whole, or may constitute a small subgroup for the purpose of these hearings;

(c) the decision of the State Council shall be final and binding.

(8) Penalties –
(a) Penalties may be imposed against any clinical establishment that contravenes any provision under this Act, or is found to have violated its terms.

(b) Authorized bodies at the district, city or state level may pursue penalties against clinical establishments found to violate any provision of this Act or the bye-laws, guidelines, norms, standards, etc. prescribed under this Act.

(c) These penalties may be monetary or non-monetary in nature.

(d) Monetary penalties shall be imposed against clinical establishments, with the rates of penalties scaled as per the category of the clinical establishment. The rates of penalties for different violations shall be as decided by the State Council, and may be updated under the Council’s discretion.

(e) Non-monetary penalties include –

(i) suspension of registration; and

(ii) cancellation of registration following failure to rectify deficiencies despite notification and issue of penalties, or chronic non-adherence to guidance presenting a risk to patients.

Provided that before imposing non-monetary penalties, due opportunity shall be given to the clinical establishment to rectify the violations and to offer an explanation regarding the same.

(f) As specified in the Act, all clinical establishments must be registered under the Independent District or City Councils, and by default the State Council, in order to operate. Consequently, clinical establishments whose registrations have been cancelled are not eligible to resume operations until the deficiencies have been rectified and the clinical establishment registers itself afresh.

(g) If a clinical establishment operates without registration, the State Council will have the power to close the clinical establishment and seize the properties.
(h) In clinical establishments functioning under the supervision of a hospital board, the members of the board may be held accountable for the quality of care provided in cases of chronic institutional malpractices.

(1) If any difficulty arises in giving effect to the provisions of this Act, the State Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as appear to it to be necessary or expedient for removal of the difficulty: provided that no such order shall be made after the expiry of a period of two years from the date of the commencement of this Act.

(2) Every order made under this section shall, as soon as practicable, be laid before both Houses of Legislature.

The Andhra Pradesh Private Medical Care Establishments (Registration and Regulation) Act, 2002 stands repealed.

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